

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

MEDA PHARMACEUTICALS INC.,	)	
Plaintiff,	)	
	)	
vs.	)	
	)	
APOTEX INC. and APOTEX CORP.,	)	Civil Action No. 06-164-SLR
Defendants.	)	
	)	

**JOINT PRETRIAL ORDER**

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Dated: April 18, 2008

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On April 21, 2008, at 2:00 p.m., counsel for Plaintiff Meda Pharmaceuticals Inc., formerly known as MedPointe Healthcare Inc. ("Plaintiff"), and counsel for Defendants Apotex Inc. and Apotex Corp. (collectively "Defendants") will participate in the final pretrial conference before this Court pursuant to Rule 16 of the Federal Rules of Civil Procedure and Local Rule 16.3 of this Court. The following matters as to trial of this action, commencing on May 5, 2008, are hereby ordered by the Court.

## **I. NATURE OF THE ACTION AND THE PLEADINGS**

### **A. The Pleadings**

1. On March 10, 2006, Plaintiff filed suit against Defendants alleging: (1) that Defendants' submission of Abbreviated New Drug Application ("ANDA") 77-954 to the FDA, seeking approval to market a generic nasal spray product containing 0.1% azelastine hydrochloride (the "Generic Product"), and including an allegation under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act (a "Paragraph IV Certification") against U.S. Patent No. 5,164,194 ("the '194 patent") constituted an act of infringement of the '194 patent under 35 U.S.C. § 271(e)(2)(A); (2) that if Defendants were to commercially manufacture, use, offer to sell, sell or import the Generic Product, or induce or contribute to any such conduct, it would further infringe the '194 patent under 35 U.S.C. § 271(a), (b) and/or (c); and (3) that this an exceptional case under 35 U.S.C. § 285. (D.I. 1).

2. On March 13, 2006, prior to receiving a responsive pleading from Defendants, Plaintiff filed an Amended Complaint raising the same allegations of infringement as in its original Complaint. (D.I. 5).

3. On April 14, 2006, Defendants filed the Answer Of Apotex Inc. And Apotex Corp. To Plaintiff's Amended Complaint, Affirmative Defenses, And Counterclaims, in which they denied Plaintiff's allegations of infringement; asserted invalidity of the '194 patent under 35 U.S.C. §§ 101, 102, 103 and 112, unenforceability of the '194 patent due to inequitable

conduct in the course of its prosecution, and misuse of the '194 patent as defenses; and sought a declaratory judgment of invalidity and/or unenforceability of the '194 patent and attorney fees and costs under 35 U.S.C. § 285. Defendants also made a demand for a jury trial. (D.I. 11).

4. Defendants deny that they are currently involved in the commercial manufacture, use, offer for sale, sale or importation of an azelastine hydrochloride nasal spray into the United States and, therefore, deny that they are infringing the claims of the '194 patent directly or currently inducing or contributing to the infringement of the claims of the '194 patent under 35 U.S.C. §§ 271(a), (b) & (c). Defendants further deny that this is an exceptional case under 35 U.S.C. § 285.

5. Plaintiff contends that Defendants will commercially manufacture, use, offer for sale, sell and import the Generic Product into the United States upon approval by the FDA of ANDA 77-954 and will therefore infringe the '194 patent under 35 U.S.C. § 271(a), (b) and/or (c).

6. On May 4, 2006, Plaintiff answered Defendants' Counterclaims, denying the allegations of invalidity and unenforceability therein, and denying that Defendants are entitled to attorney fees and costs. (D.I. 15). On May 5, 2006, Plaintiff filed a Corrected Reply To Defendants' Counterclaims To Amended Complaint. (D.I. 18)

7. On May 4, 2006, Plaintiff moved to strike Defendants' jury demand, strike Defendants' affirmative defenses of unenforceability and patent misuse, and dismiss Defendants' counterclaim of unenforceability. (D.I. 17).

8. On May 19, 2006, Defendants withdrew their demand for a jury trial without prejudice. (D.I. 21).



9. On January 26, 2007, after it had been fully briefed, the Court denied Plaintiff's motion to strike Defendants' affirmative defenses of unenforceability and patent misuse, and dismiss Defendants' counterclaim of unenforceability. (D.I. 47).

B. Motions / Issues Pending Before the Court

1. The parties' opening and answering claim construction briefs are presently pending before the Court. (D.I. 102, 103, 112, 113). In addition, Defendants' Motion To Supplement Apotex's Response Brief On Claim Construction, filed February 26, 2008 (D.I. 121, 122), is presently pending before the Court. Plaintiff filed its Answering Brief In Opposition To Apotex's Motion To Add New Arguments To Apotex's Claim Construction Papers on March 14, 2008. (D.I. 124). Defendants filed Apotex's Reply In Support Of Its Motion To Supplement Apotex's Response Brief On Claim Construction on March 25, 2008. (D.I. 126).

2. The parties have executed a Stipulated Findings of Fact regarding infringement issues and sales of the Meda product covered by the patent-in-suit. The parties jointly and respectfully seek entry of these Stipulated Findings Of Fact, which have been filed with the Court concurrently herewith.

3. Defendants have informed Plaintiff that they intend to serve supplemental expert reports relying on materials reviewed by their experts subsequent to the experts' depositions and that have not been identified or provided to Plaintiff to date. Plaintiff intends to object and move to strike these supplemental expert reports and intends to oppose any testimony offered by Apotex's experts relying on these additional materials.

4. The parties have executed a Stipulation Regarding Name Change And Case Caption regarding Plaintiff's change of name from MedPointe Healthcare Inc. to Meda Pharmaceuticals Inc. The parties jointly and respectfully seek entry of this Stipulation Regarding Name Change And Case Caption, which was filed with the Court on April 17, 2008. (D I. 132).

C. Motions In Limine

1. Under the Court's June 14, 2006 Rule 16 Scheduling Order (D.I. 31) and June 5, 2007 Amended Rule 16 Scheduling Order (D.I. 85), no motions in limine may be filed at this time.

2. The parties reserve the right to address any evidentiary issues at the pretrial conference and during trial.

D. Designation Of Corporate Representatives

The parties agree that each side may designate one corporate employee as their corporate representatives to sit through the entire trial of the above-captioned action, and that such corporate representatives may also be called as fact witnesses during the trial; provided, however, that any such corporate representative called as a fact witness has previously been identified by the party as a fact witness in accordance with Paragraph 2(g) of the Rule 16 Scheduling Order. (D.I. 31).

II. BASES FOR FEDERAL JURISDICTION

A. Plaintiff Meda Pharmaceuticals Inc., formerly known as MedPointe Healthcare Inc., is a Delaware corporation having a place of business at 265 Davidson Avenue, Somerset, New Jersey 08873.

B. Defendant Apotex Inc. is a corporation organized and existing under the laws of Canada having a place of business at 380 Elgin Hills Road East, Richmond Hill, Ontario, Canada L4C 5H2.

C. Defendant Apotex Corp. is a Delaware corporation having a place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

D. This action for patent infringement arises under the patent laws of the United States, 35 U.S.C. § 271, *et seq*. This Court has subject matter jurisdiction over this action under

28 U.S.C. §§ 1331 and 1338(a). Subject matter jurisdiction over the counterclaims is also based on 28 U.S.C. §§ 2201 and 2202.

E. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b)-(d) and § 1400(b). No party contests venue or personal jurisdiction.

### **III. STATEMENT OF ADMITTED FACTS**

The parties admit the facts stated in attached Exhibit 1. These admitted facts require no proof at trial.

### **IV. STATEMENTS OF ISSUES OF FACT REMAINING TO BE LITIGATED**

A. Plaintiff's statement of issues of fact that remain to be litigated is attached as Exhibit 2.

B. Defendants' statement of issues of fact that remain to be litigated is attached as Exhibit 3.

### **V. STATEMENTS OF ISSUES OF LAW REMAINING TO BE LITIGATED**

A. Plaintiff's statement of issues of law that remain to be litigated is attached as Exhibit 4.

B. Defendants' statement of issues of law that remain to be litigated is attached as Exhibit 5.

### **VI. EXHIBITS**

A. Plaintiff's preliminary list of exhibits that it intends to offer at trial, except solely for impeachment (other than demonstrative exhibits) is attached as Exhibit 14. Defendants' objections to Plaintiff's list of exhibits, except as to the accuracy of translations, is attached as Exhibit 17.

B. Defendants' preliminary list of exhibits that they intend to offer at trial, except solely for impeachment (other than demonstrative exhibits) is attached as Exhibit 15. Plaintiff's

objections to Defendants' list of exhibits, except as to the accuracy of translations, is attached as Exhibit 16.

C. The parties reserve the right to supplement their respective exhibit lists, with sufficient notice to the other side and opportunity to object.

D. The parties will offer as exhibits at trial one or more of the exhibits set forth on their respective exhibit lists. These lists include the exhibit number to be used at trial and a description sufficient to identify the exhibit, *i.e.*, by production number, deposition exhibit number or otherwise, for review and possible objection. The parties reserve the right to offer rebuttal or impeachment exhibits that are not set forth on their exhibit lists, depending on the testimony of the other side's witnesses.

E. Any party may use an exhibit that is listed on another party's exhibit list, to the same effect as though it were on its own exhibit list, subject to all evidentiary objections. Any exhibit, once admitted, may be used equally by any party, subject to any specific objections with respect to the particular witness for whom the exhibit is being offered.

F. Any exhibit identified on any party's exhibit list and not objected to, may be admitted and entered in evidence, except over an objection of relevance or foundation. Each party herein expressly reserves the right to object to the relevancy or foundation of any evidence offered by the other parties, at the time such evidence is offered, in view of the specific context in which, and the specific witness by which, such evidence is offered.

G. Legible photocopies of the '194 patent, its file wrapper, and the applications to which it claims priority, are admissible into evidence, in lieu of certified copies thereof. However, if available as exhibits, a certified copy of the '194 patent, its file wrapper, and the applications to which it claims priority shall be admissible into evidence in lieu of uncertified photocopies.

H. Legible photocopies of United States patents and the contents of the Patent and Trademark Office file histories may be offered and received in evidence in lieu of certified copies thereof, subject to all other objections which might be made to the admissibility of certified copies. The dates of filing and issuance shall be deemed to be shown on the face of the patent, subject to the right of the party against whom it is offered to adduce evidence to the contrary. However, if available as exhibits, certified copies of United States patents and the certified contents of the Patent and Trademark Office file histories shall be received in evidence, in lieu of uncertified photocopies, subject to all other objections which might be made to the admissibility of the certified copies.

I. Legible photocopies of printed publications may be offered and received in evidence in lieu of originals thereof, subject to all foundational requirements and other objections which might be made to the admissibility of such originals. Each such document shall be deemed *prima facie* to have been published on the date it bears (if any), subject to the right of the party against whom it is offered to adduce evidence to the contrary.

J. Legible photocopies of other documents may be offered and received in evidence in lieu of originals thereof, subject to all foundational requirements and other objections which might be made to the admissibility of such originals. Each party will provide notification to the other party by April 23, 2008 of any exhibits for which a request to view the original may be made. Each such document shall be deemed *prima facie* to have been created on the date it bears (if any), subject to the right of the party against whom it is offered to adduce evidence to the contrary.

K. Any document that on its face appears to have been authored by an employee, officer or agent of a party shall be deemed *prima facie* to be authentic, subject to the right of the party against whom such a document is offered to adduce evidence to the contrary. Each party

will provide notification to the other party by April 23, 2008 of any such exhibits for which a request to view the original may be made.

L. Any document that on its face was authored or prepared by a third party that was produced in discovery by a party, if offered by the opposing party, shall be deemed *prima facie* to be authentic, subject to the right of the party against whom such a document is offered to adduce evidence to the contrary. Each party will provide notification to the other party by April 23, 2008 of any such exhibits for which a request to view the original may be made.

M. Exhibits and Demonstratives To Be Used During Opening Arguments: The parties shall identify any trial exhibits and shall identify and serve copies of any demonstrative exhibits (in color, and on 8½" x 11" paper or larger) to be used in opening arguments before such arguments. This identification and service by each party shall occur by 7:00 p.m. on May 2, 2008. Final objections to evidentiary and demonstrative exhibits identified for use during opening arguments shall be made by each party by 7:00 pm on May 3, 2008. The parties shall meet and confer in an attempt to resolve any objections to exhibits that are identified for use in opening arguments.

N. The parties agree that the demonstrative exhibits the parties intend to use at trial do not need to be included on their respective lists of trial exhibits. Demonstratives used at trial will be given exhibit numbers. Demonstrative exhibits to be used with a witness on direct shall be disclosed to opposing counsel by 7:00 p.m. on the day before they are to be used. Any objections to demonstrative exhibits shall be made by 9:00 p.m. the day that the demonstrative exhibits are served. The parties shall meet and confer in an attempt to resolve any objections to the demonstrative exhibits that are expected to be used during direct examination.

O. The parties shall make available for prior inspection physical exhibits to be used at trial, labeled with the exhibit number.

**VII. WITNESSES TO BE CALLED IN PERSON OR BY DEPOSITION**

A. Plaintiff's list of witnesses that it intends to call at trial is attached as Exhibit 6.

B. Defendants' list of witnesses that they intend to call at trial is attached as Exhibit 7.

C. Demonstratives To Be Used During Direct Examination of Witnesses: The parties shall identify (by witness) and serve copies of any demonstrative exhibits (in color, and on 8½" x 11" paper or larger) to be used in direct examination of a witness by 7:00 p.m. the day before the direct examination is expected to take place.

D. The notice provisions of this paragraph shall not apply to demonstrative exhibits created in the courtroom during direct testimony at trial. Any objections to demonstrative exhibits shall be made by 9:00 p.m. the day that the demonstrative exhibits are served. The parties shall meet and confer in an attempt to resolve any objections to the demonstrative exhibits that are expected to be used during direct examination.

E. Exhibits To Be Used During Direct Examination Of Witnesses: The parties shall identify the trial exhibits they expect to use on direct examination by 6:00 p.m. two days before the direct examination is expected to take place. Final objections to exhibits shall be made by 9:00 p.m. two days before the direct examination is expected to take place. The parties shall meet and confer in an attempt to resolve any objections to the trial exhibits that are expected to be used during direct examination.

F. Notwithstanding ¶ VII.E above, the parties may identify additional trial exhibits that they expect to use on direct examination of a witness by 7:00 p.m. one day prior to the date the witness is to be called, if such additional exhibits relate to testimony directed to the testimony of another witness who testifies one day before the witness is expected to be called.

G. Deposition Designations. As noted in Section VIII below, the parties have provided each other with notice of the witnesses that they expect to call by deposition.



H. If a party plans to reduce the scope of deposition testimony previously designated, the party shall provide notice by 7:00 p.m. two days prior to the date it expects to introduce such testimony. By 7:00 p.m. on the day following notice, the parties shall meet and confer in an attempt to resolve any objections regarding the designated testimony and any changes to counter-designations and counter-counter-designations that may be required.

I. Subject to instruction from the Court regarding whether deposition testimony shall be read or played in open court, the following provisions shall apply to deposition testimony the Court desires read or played in open Court:

1. If a party designates deposition testimony, and the other party counter-designates, both the designations and counter-designations (and any counter-counter-designations) will be read or played.
2. The time available for each party's presentation shall be reduced by the length of its designations, counter-designations, or counter-counter-designations.
3. All designated portions of the deposition shall be read or played in page, line order.

J. Translations. The parties shall identify and serve copies of any translations of trial exhibits that they expect to introduce at trial. Service shall occur by 7:00 p.m. seven days before the translation is expected to be used. If the opposing party disagrees with the accuracy of the translation, they shall serve corrections by 7:00 p.m. five days after service. The parties shall meet and confer in an attempt to resolve any disagreements regarding the accuracy of the translation. Evidentiary objections to a trial exhibit shall also apply to any corresponding translation.

## **VIII. DESIGNATIONS**

A. The parties' discovery designations (interrogatories and answers thereto; and requests for admission and answers thereto) are included on their respective exhibit lists.



B. Plaintiff's deposition designations, with Defendants' counter-designations and objections and any counter-counter designations by Plaintiff, are attached as Exhibit 12.

C. Defendants' deposition designations, with Plaintiff's counter-designations and objections and any counter-counter designations by Defendants, are attached as Exhibit 13.

**IX. BRIEF STATEMENT OF INTENDED PROOFS**

A. In support of its claims, in addition to the facts not in dispute, Plaintiff expects to offer the proofs set forth in Exhibit 8.

B. In support of its defenses and counterclaims, in addition to the facts not in dispute, Defendants expect to offer the proofs set forth in Exhibit 9.

**X. MISCELLANEOUS ISSUES**

A. Plaintiff's miscellaneous issues are set forth in Exhibit 10.

B. Defendants' miscellaneous issues are set forth in Exhibit 11.

**XI. CERTIFICATE OF ATTEMPTED RESOLUTION OF CONTROVERSY**

The parties certify that two-way communication has occurred between persons having authority in a good faith effort to explore the resolution of the controversy by settlement. No agreement has been reached.

**XII. ORDER TO CONTROL COURSE OF ACTION**

This Order shall control the subsequent course of this action, unless modified by the Court to prevent manifest injustice.

**JOINTLY SUBMITTED BY:**

/s/Kelly E. Farnan

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Dated: April 18, 2008

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SO ORDERED this \_\_\_\_\_ day of April, 2008.

\_\_\_\_\_  
United States District Judge

# **EXHIBIT 1**

EXHIBIT 1

**STATEMENT OF ADMITTED FACTS**

**I. THE PARTIES**

A. Plaintiff Meda Pharmaceuticals Inc., formerly known as MedPointe Healthcare Inc., is a Delaware corporation having a place of business at 265 Davidson Avenue, Somerset, New Jersey 08873.

B. Defendant Apotex, Inc. is a corporation organized and existing under the laws of Canada having a place of business at 380 Elgin Hills Road East, Richmond Hill, Ontario, Canada L4C 5H2.

C. Defendant Apotex, Corp. is a Delaware corporation having a place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

**II. PATENTS**

A. On November 17, 1992, U.S. Patent 5,164,194 ("the '194 patent"), titled "Azelastine Containing Medicaments" was issued, naming Helmut Hettche as inventor and Asta Pharma AG as assignee. Application No. 551,644 for the '194 patent was filed on July 12, 1990.

B. Meda is the sole owner of the '194 patent. To the extent that the '194 patent is valid and enforceable, Meda has the right to sue and recover for any infringement of that patent.

C. The '194 patent is a continuation of U.S. application 268,772, filed on November 9, 1988, and subsequently abandoned.

D. The '194 patent claims priority to German application 3738681, which was filed on November 13, 1987, which claim Apotex does not contest.

E. The '194 patent was granted a patent term extension of 349 days under 35 U.S.C. § 156.

F. Meda holds New Drug Application ("NDA") 20-114 on ASTELIN<sup>®</sup> brand azelastine hydrochloride nasal spray, which NDA was approved by the U.S. Food and Drug Administration ("FDA") on November 1, 1996.

G. ASTELIN<sup>®</sup> brand 0.1% azelastine hydrochloride nasal spray qualifies for six months of pediatric exclusivity after expiration of the '194 patent, as extended.

H. With the § 156 patent term extension, the six months of pediatric exclusivity granted by the U.S. Food and Drug Administration prevents a generic version of ASTELIN<sup>®</sup> brand 0.1% azelastine hydrochloride nasal spray from being marketed in the United States before May 1, 2011, unless it is found not to infringe any valid and enforceable asserted claim of the '194 patent.

### **III. SCIENTIFIC FACTS**

- A. Azelastine hydrochloride is a salt form of the active ingredient azelastine.
- B. Azelastine hydrochloride is a physiologically acceptable salt of azelastine.
- C. Alkylbenzyldimethyl ammonium chloride, also known as benzalkonium chloride, is a pharmaceutically usable preservative.

### **IV. CLAIM CONSTRUCTION**

A. Abbreviated New Drug Application ("ANDA") 77-954 seeks the approval from the United States Food and Drug Administration ("FDA") necessary to engage in the commercial manufacture, use, offer for sale and sale of a generic nasal spray product containing 0.1% azelastine hydrochloride.

B. For purposes of this action, the claim term "method for the treatment of" means "Treatments that address symptoms and/or treatments that address the underlying cause of disease."

C. For purposes of this action, the claim term "sodium-2-(ethylmercurithio)-benzoate means "A preservative commonly referred to as thimerosal."

D. For purposes of this action, the claim term "alkylbenzyltrimethyl ammonium chloride" means "A preservative commonly referred to as benzalkonium chloride."

## **V. INFRINGEMENT**

A. Use of Meda's ASTELIN® brand azelastine hydrochloride nasal spray for the treatment of the symptoms of seasonal allergic rhinitis or the symptoms of vasomotor rhinitis falls within the scope of Claims 4, 5, 7, 8 and 9 of the '194 patent.

B. Apotex's filing of Abbreviated New Drug Application ("ANDA") 77-954 for a generic azelastine hydrochloride nasal spray, which ANDA included a Paragraph IV Certification under §505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, constitutes a technical act of infringement of the '194 patent pursuant to 35 U.S.C. §271(e)(2)(A). If commercially made, used, offered for sale or sold within the United States, or commercially imported into the United States, for the treatment of the symptoms of seasonal allergic rhinitis or the symptoms of vasomotor rhinitis, Apotex's proposed generic azelastine hydrochloride nasal spray would also literally infringe, induce literal infringement and/or contribute to literal infringement of Claims 4, 5, 7, 8 and 9 of the '194 patent to the extent that those claims are valid and enforceable.

## **VI. COMMERCIAL SUCCESS**

From November 1996 through December 2007, U.S. sales of ASTELIN® have totaled over \$961 million. During the twelve months ending December 31, 2007, U.S. sales of ASTELIN® totaled over \$188 million.

**VII. THE PROPOSED APOTEX GENERIC PRODUCT**

A. As of this time, Apotex's proposed generic product, which is described in ANDA 77-954, has yet to receive tentative or final approval by the U.S. Food and Drug Administration ("FDA").

B. In the absence of tentative or final approval, Apotex cannot launch the proposed generic product described in ANDA 77-954 regardless of the existence or outcome of this action.

## **EXHIBIT 2**



EXHIBIT 2

**PLAINTIFF'S STATEMENT OF ISSUES  
OF FACT THAT REMAIN TO BE LITIGATED**

Plaintiff respectfully submits the following list of issues of fact that remain to be litigated. Should the Court determine that any issue identified in this list as an issue of fact is more properly considered an issue of law, it should be so considered. Plaintiff reserves the right to revise this list in light of the Court's decisions on claim construction.

- A. Plaintiffs have asserted infringement of Claims 4, 5, 7, 8 and 9 of the '194 patent.
- B. Defendants admit this infringement in the Stipulated Findings of Fact jointly submitted to the Court. Upon entry of these Stipulated Findings of Fact, Plaintiff has met its burden of proving no further infringement issue needs to be tried.

**I. VALIDITY OF THE ASSERTED CLAIMS OF THE '194 PATENT**

Whether Defendants can prove by clear and convincing evidence that Claims 4, 5, 7, 8 and 9 of the '194 patent are invalid.

- A. Prior Art. Whether Defendants can prove by clear and convincing evidence that each of the references upon which they rely qualifies as prior art.
- B. Anticipation. Whether Defendants can prove by clear and convincing evidence that: (1) a single prior art reference discloses all of the elements of any asserted claim of the '194 patent; and (2) does so in a way that enabled a person of ordinary skill in the art to make and use the claimed invention without undue experimentation.
- C. Obviousness. Whether Defendants can prove by clear and convincing evidence that the invention described in any asserted claim of the '194 patent was obvious to a person of ordinary skill in the art at the time the claimed invention was made

in light of the scope and content of the prior art, the differences between such claim and the prior art, the level of ordinary skill in the art at that time, and the objective evidence of nonobviousness.

#### **VIII. ENFORCEABILITY OF THE '194 PATENT**

Whether Defendants can prove by clear and convincing evidence that the '194 patent is unenforceable.

- A. Alleged Misrepresentation Or Nondisclosure. Whether Defendants can prove by clear and convincing evidence that, during prosecution of the '194 patent, any alleged misrepresentation or nondisclosure to the Patent and Trademark Office ("PTO") occurred.
- B. Materiality. Whether Defendants can prove by clear and convincing evidence that each alleged nondisclosure or misrepresentation upon which they rely was material to the patentability of the subject matter claimed in the '194 patent.
- C. Intent. Whether Defendants can prove by clear and convincing evidence that each alleged nondisclosure or misrepresentation upon which they rely was made with the intent to deceive the PTO.
- D. Balancing. Whether Defendants can prove by clear and convincing evidence that alleged misrepresentation or nondisclosure to the PTO was material and made with the intent to deceive the PTO, on balance, warrants a holding that the '194 patent is unenforceable.

#### **IX. MISUSE OF THE '194 PATENT**

Whether Defendants can prove by clear and convincing evidence that Plaintiff has misused the '194 patent.

**X. EXCEPTIONAL CASE**

Whether this case is exceptional under 35 U.S.C. § 285.

## EXHIBIT 3

Exhibit 3

EXHIBIT 3

**DEFENDANTS' STATEMENT OF ISSUES  
OF FACT THAT REMAIN TO BE LITIGATED**

Defendants respectfully submit the following list of issues of fact that remain to be litigated. Should the Court determine that any issue identified in this list as an issue of fact is more properly considered an issue of law, it should be treated as an issue of law as if it had been listed by Defendants in Exhibit 5. Defendants reserve the right to revise this list in light of the Court's decisions on claim construction.

**I. Infringement.**

1. Upon entry of the Stipulated Findings of Fact, the issue of infringement of Claims 4, 5, 7, 8, and 9 of the '194 patent will not need to be tried.

**II. Invalidity.**

1. Whether Claims 1–12 of the '194 patent are invalid for anticipation under 35 U.S.C. § 102.

**A. Obviousness.**

1. Whether the subject matter as a whole defined in each of Claims 1–12 of the '194 patent would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

**1. Level of Ordinary Skill in the Art.**

1. The legal question of obviousness subsumes a factual question about level of ordinary skill in the art, to be determined based on factors including (1) the educational level of the inventor; (2) type of problems encountered in the art; (3) prior art solutions to those problems; (4) rapidity with which innovations are made; (5) sophistication of the technology;

and (6) educational level of active workers in the field. The level of ordinary skill in the art can determine the relevance and significance of prior art cited.

**2. Scope and Content of the Prior Art**

1. The legal question of obviousness also subsumes a factual question about the scope and content of the prior art.

**3. Differences Between Prior Art and the Subject Matter Claims**

1. In addressing the legal question of obviousness, the Court must also consider the factual question of ascertaining the differences between the prior art and the claims at issue.

2. Whether the alleged differences from the prior art reflect the application of known techniques or a predictable variation on known techniques such as to bar patentability.

3. Whether the alleged differences from the prior art were obvious to try, reflecting finite number of known options within the technical grasp of a person of ordinary skill.

**4. Relevant Secondary Considerations**

1. In addressing the legal question of obviousness, the Court may also consider secondary considerations as indicia of obviousness or non-obviousness, including commercial success, long felt but unsolved needs, failure of others, etc.

**5. Nexus**

1. The legal question of obviousness also requires the Court to determine factual issues relating to whether alleged secondary considerations are pertinent evidence properly attributable to the merits of the claimed subject matter, or whether instead other factors explaining such considerations cannot be excluded.

2. Whether alleged secondary considerations are attributable to features not claimed or present in the prior art.

3. Whether the patentee has shown that alleged secondary considerations were due to anything disclosed in the '194 patent which was not readily available in the prior art.

4. Whether any alleged secondary considerations such as commercial success could be the product of factors such as having first FDA approval or marketing efforts, which are not relevant as indicia of patentability.

**6. Reasonable Expectation of Success**

1. Whether the prior art afforded one of ordinary skill in the art a reasonable expectation of success as to the subject matter in each of Claim 1–12 of the '194 patent, even if success was not guaranteed or assured.

**B. Anticipation.**

1. The legal question of validity includes a determination of validity concerning anticipation under 35 U.S.C. § 102, which is generally considered a question of fact but may also pose questions of law on some issues and questions of the application of law to facts.

2. Whether for purposes of anticipation every element of the subject matter in the anticipated claim is to be found expressly or inherently in a single reference.

3. Whether elements that are not recited explicitly or expressly *in haec verba* are nonetheless within the scope of disclosure that a reference would enable because those elements are inherent in the subject matter disclosed (such as the inherent properties of disclosed subject matter) or because they are within the general knowledge that one of ordinary skill of the art brings to an examination of the particular reference.

### **III. Unenforceability for Inequitable Conduct**

1. Whether the '194 patent is unenforceable for inequitable conduct during the prosecution of the patent in the United States Patent and Trademark Office.
2. Whether the patentee misrepresented or failed to disclose material information with the intent to deceive the PTO.

### **IV. Misuse**

1. Whether the patentee has engaged in misuse, regardless of whether the conduct constituting misuse would amount to an antitrust violation.
2. Whether, by imposing conditions that derive their force from the patent, the patentee has impermissibly broadened the scope of the patent grant with anticompetitive effect.
3. Whether the patentee has engaged in practices that draw anticompetitive strength from the patent right, regardless of whether the practices themselves violate any laws, and thus are deemed contrary to public policy.
4. Whether the patentee has used the patent to obtain market benefit beyond that which inures to in the statutory patent right.
5. Whether the patentee has used patent rights to obtain or coerce an unfair commercial advantage.
6. Whether the patentee, although acting under color of law, has nevertheless engaged in improper activities in obtaining the patent by defrauding the patent office.

### **V. Exceptional Case**

1. Whether this is an exceptional case within the meaning of 35 U.S.C. § 285, which would permit the award of attorneys fees to the prevailing party under?



2. Whether under the totality of the circumstances the district court should exercise its discretion in this case to award attorneys fees to the prevailing party?

3. If the patentee prevails, whether Apotex Corp. or Apotex Inc., jointly or severally, engaged in any conduct that could be the basis for an exceptional case determination and an award of attorneys fees, which cannot be predicated on the mere fact that a company has filed an ANDA application or certification?

## **EXHIBIT 4**

EXHIBIT 4

**PLAINTIFF'S STATEMENT OF ISSUES  
OF LAW THAT REMAIN TO BE LITIGATED**

Plaintiff respectfully submits the following list of issues of law that remain to be litigated. Should the Court determine that any issue identified in this list as an issue of law is more properly considered an issue of fact, it should be so considered.

- A. Plaintiffs have asserted infringement of Claims 4, 5, 7, 8 and 9 of the '194 patent.
- B. Defendants admit this infringement in the Stipulated Findings of Fact jointly submitted to the Court. Upon entry of these Stipulated Findings of Fact, Plaintiff has met its burden of proving no further infringement issue needs to be tried.

**I. VALIDITY OF THE ASSERTED CLAIMS OF THE '194 PATENT**

Whether Defendants can prove by clear and convincing evidence that Claims 4, 5, 7, 8 and 9 of the '194 patent are invalid. *Atl. Thermoplastics Co. v. Faytex Corp.*, 5 F.3d 1477 (Fed. Cir. 1993).

A. Prior Art. Whether Defendants can prove by clear and convincing evidence that each of the references upon which they rely qualifies as prior art. *N. Telecom, Inc. v. Datapoint Corp.*, 908 F.2d 931 (Fed. Cir. 1990).

A. Anticipation. Whether Defendants can prove by clear and convincing evidence that: (1) a single prior art reference discloses all of the elements of any asserted claim of the '194 patent; and (2) does so in a way that enabled a person of ordinary skill in the art to make the claimed invention without undue experimentation. 35 U.S.C. § 102; *Glaxo Group Ltd. v. Apotex, Inc.*, 376 F.3d 1339 (Fed. Cir. 2004).

B. Obviousness. Whether Defendants can prove by clear and convincing evidence that the invention described in any asserted claim of the '194 patent was obvious to a person of

ordinary skill in the art at the time the claimed invention was made in light of the scope and content of the prior art, the differences between such claim and the prior art, the level of ordinary skill in the art at that time, and the objective evidence of nonobviousness. 35 U.S.C. § 103(a); *KSR Intern. Co. v. Teleflex Inc.*, 127 S.Ct. 1727 (2007); *Graham v. John Deere Co.*, 383 U.S. 1 (1966); *Takeda Chemical Industries, Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350 (Fed. Cir. 2007).

## II. ENFORCEABILITY OF THE '194 PATENT

Whether Defendants can prove by clear and convincing evidence that the '194 patent is unenforceable. *Mentor H/S, Inc. v. Medical Device Alliance, Inc.*, 244 F.3d 1365 (Fed. Cir. 2001).

A. Alleged Misrepresentation Or Nondisclosure. Whether Defendants can prove by clear and convincing evidence that, during prosecution of the '194 patent, any alleged misrepresentation or nondisclosure to the PTO occurred. *Young v. Lumenis, Inc.*, 492 F.3d 1336 (Fed. Cir. 2007).

B. Materiality. Whether Defendants can prove by clear and convincing evidence that each alleged nondisclosure or misrepresentation upon which they rely was material to the patentability of the subject matter claimed in the '194 patent. *Impax Laboratories, Inc. v. Aventis Pharmaceuticals Inc.*, 468 F.3d 1366 (Fed. Cir. 2006).

C. Intent. Whether Defendants can prove by clear and convincing evidence that each alleged nondisclosure or misrepresentation upon which they rely was made with the intent to deceive the PTO. *Warner-Lambert Co. v. Teva Pharmaceuticals USA, Inc.*, 418 F.3d 1326 (Fed. Cir. 2005).

**III. MISUSE OF THE '194 PATENT**

Whether Defendants can prove by clear and convincing evidence that Plaintiff has misused the '194 patent. *Mentor H/S, Inc. v. Medical Device Alliance, Inc.*, 244 F.3d 1365 (Fed. Cir. 2001),

**IV. EXCEPTIONAL CASE**

Whether this case is "exceptional" under 35 U.S.C. § 285. *Yamanouchi Pharm., Co. Ltd. v. Danbury Pharmacal, Inc.*, 231 F.3d 1339 (Fed. Cir. 2000).

## **EXHIBIT 5**

EXHIBIT 5

**DEFENDANTS' STATEMENT OF ISSUES OF LAW  
THAT REMAIN TO BE LITIGATED**

Defendants submit the following statement of issues of law that remain to be litigated. To the extent that an issue of law identified below is considered by the Court to more properly present an issue of fact, it should be treated as an issue of fact as if it had been listed by Defendants in Exhibit 3.

**I. Infringement.**

1. Upon entry of the Stipulated Findings of Fact, the issue of infringement of Claims 4, 5, 7, 8, and 9 of the '194 patent will not need to be tried.

**II. Invalidity.**

1. Whether Claims 1–12 of the '194 patent are invalid under one or more of the grounds set for in the Title 35, United States Code.

**A. Obviousness.**

1. Whether the subject matter as a whole defined in each of Claims 1–12 of the '194 patent would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

**1. Level of Ordinary Skill in the Art.**

1. The legal question of obviousness subsumes a factual question about level of ordinary skill in the art, to be determined based on factors including (1) the educational level of the inventor; (2) type of problems encountered in the art; (3) prior art solutions to those problems; (4) rapidity with which innovations are made; (5) sophistication of the technology; and (6) educational level of active workers in the field. *Daiichi Sankyo Co., Ltd. v. Apotex, Inc.*, 501 F.3d 1254, 1256 (Fed. Cir. 2007). The level of ordinary skill in the art can determine the

relevance and significance of prior art cited. *Id.* at 1257 ("The district court's error in determining the level of ordinary skill in the art of the '741 patent tainted its obviousness analysis."); *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356, 1362 (Fed. Cir. 2006) ("Because the parties disagree over the relevance of the cited prior art, which, fundamentally, is a disagreement over the level of ordinary skill in the art, we address this third Graham factor first.").

## **2. Scope and Content of the Prior Art**

1. The legal question of obviousness also subsumes a factual question about the scope and content of the prior art.

## **3. Differences Between Prior Art and the Subject Matter Claims**

1. In addressing the legal question of obviousness, the Court must also consider the factual question of ascertaining the differences between the prior art and the claims at issue.

2. Whether the alleged differences from the prior art in reflect the application of known techniques or a predictable variation on known techniques such as to bar patentability. The principles underlying these cases are instructive when the question is whether a patent claiming the combination of elements of prior art is obvious. When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability. *KSR Intern. Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1740 (2007).



3. Whether the alleged differences from the prior art were obvious to try, reflecting finite number of known options within the technical grasp of a person of ordinary skill. *KSR Intern. Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1742 (2007).

**4. Relevant Secondary Considerations**

1. In addressing the legal question of obviousness, the Court may also consider secondary considerations as indicia of obviousness or non-obviousness, including commercial success, long felt but unsolved needs, failure of others, etc.

**5. Nexus**

1. The legal question of obviousness also requires the Court to determine whether alleged secondary considerations are pertinent evidence properly attributable to the merits of the claimed subject matter, or whether instead other factors explaining such considerations cannot be excluded.

2. Whether alleged secondary considerations are attributable to features not claimed or present in the prior art. *Ormco Corp. v. Align Technology, Inc.*, 463 F.3d 1299, 1312 (Fed. Cir. 2006).

3. Whether the patentee has shown that alleged secondary considerations were due to anything disclosed in the '194 patent which was not readily available in the prior art. *Richdel, Inc. v. Sunspool Corp.*, 714 F.2d 1573, 1580 (Fed. Cir. 1983).

4. Whether any alleged secondary considerations such as commercial success could be the product of factors such as having first FDA approval or marketing efforts, which are not relevant as indicia of patentability.

**6. Reasonable Expectation of Success**

1. Whether the prior art afforded one of ordinary skill in the art a reasonable expectation of success as to the subject matter in each of Claim 1–12 of the '194 patent, even if success was not guaranteed or assured. *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1364 (Fed. Cir. 2007).

**B. Anticipation.**

1. The legal question of validity includes a determination of validity concerning anticipation under 35 U.S.C. § 102, which is generally considered a question of fact but may also pose questions of law on some issues and questions of the application of law to facts.

2. Whether for purposes of anticipation every element of the subject matter in the anticipated claim is to be found expressly or inherently in a single reference.

3. Whether elements that are not recited explicitly or expressly *in haec verba* are nonetheless within the scope of disclosure that a reference would enable because those elements are inherent in the subject matter disclosed (such as the inherent properties of disclosed subject matter) or because they are within the general knowledge that one of ordinary skill of the art brings to an examination of the particular reference.

**III. Unenforceability for Inequitable Conduct**

1. Whether the patentee engaged in inequitable conduct during prosecution of the '194 patent so as to render the patent unenforceable. *Hoffman–La Roche, Inc. v. Promega Corp.*, 323 F.3d 1354, 1367 (Fed. Cir. 2003).

2. Whether the patentee's acts includes the submission of false and misleading material and/or omitted material facts during prosecution of the '194 patent.

#### IV. Misuse

1. Whether the patentee has engaged in misuse, regardless of whether the conduct constituting misuse would amount to an antitrust violation. *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1372 (Fed. Cir. 1998) ("Patent misuse is viewed as a broader wrong than antitrust violation because of the economic power that may be derived from the patentee's right to exclude. Thus misuse may arise when the conditions of antitrust violation are not met."); *Monsanto Co. v. Scruggs*, 459 F.3d 1328, \*1339 (Fed. Cir. 2006).

2. Whether, by imposing conditions that derive their force from the patent, the patentee has impermissibly broadened the scope of the patent grant with anticompetitive effect. *C.R. Bard, Inc. v. M3 Systems, Inc.*, 157 F.3d 1340, 1372 (Fed. Cir. 1998) ("The key inquiry is whether, by imposing conditions that derive their force from the patent, the patentee has impermissibly broadened the scope of the patent grant with anticompetitive effect.").

3. Whether the patentee has engaged in practices that draw anticompetitive strength from the patent right, regardless of whether the practices themselves violate any laws, and thus are deemed contrary to public policy. *Mallinckrodt, Inc. v. Medipart, Inc.*, 976 F.2d 700, 704 (Fed. Cir. 1992) ("The concept of patent misuse arose to restrain practices that did not in themselves violate any law, but that drew anticompetitive strength from the patent right, and thus were deemed to be contrary to public policy.").

4. Whether the patentee has used the patent to obtain market benefit beyond that which inures to in the statutory patent right. *Monsanto Co. v. Scruggs*, 459 F.3d 1328, 1339 (Fed. Cir. 2006); *Monsanto Co. v. McFarling*, 363 F.3d 1336, 1341 (Fed. Cir. 2004); *Mallinckrodt, Inc. v. Medipart, Inc.*, 976 F.2d 700, 704 (Fed. Cir. 1992) ("The policy purpose was to prevent a patentee from using the patent to obtain market benefit beyond that which inheres in the statutory

patent right."); *See also, C.R. Bard, Inc. v. M3 Systems, Inc.*, 157 F.3d 1340, 1372 (Fed. Cir. 1998) ("Patent misuse relates primarily to a patentee's actions that affect competition in unpatented goods or that otherwise extend the economic effect beyond the scope of the patent grant.").

5. Whether the patentee has used patent rights to obtain or coerce an unfair commercial advantage. *C.R. Bard, Inc. v. M3 Systems, Inc.*, 157 F.3d 1340, 1372 (Fed. Cir. 1998) ("The defense of patent misuse arises from the equitable doctrine of unclean hands, and relates generally to the use of patent rights to obtain or to coerce an unfair commercial advantage.").

6. Whether the patentee, although acting under color of law, has nevertheless engaged in improper activities in obtaining the patent by defrauding the patent office. *Unitherm Food Systems, Inc. v. Swift-Eckrich, Inc.*, 375 F.3d 1341, 1356 (Fed. Cir. 2004)

#### **V. Exceptional Case**

1. Whether this is an exceptional case within the meaning of 35 U.S.C. § 285, which would permit the award of attorneys fees to the prevailing party?

2. Whether under the totality of the circumstances the district court should exercise its discretion in this case to award attorneys fees to the prevailing party?

3. If the patentee prevails, whether Apotex Corp. or Apotex Inc., jointly or severally, engaged in any conduct that could be the basis for an exceptional case determination and an award of attorneys fees, which cannot be predicated on the mere fact that a company has filed an ANDA application or certification? *Glaxo Group Ltd. v. Apotex, Inc.*, 376 F.3d 1339, 1350–51 (Fed. Cir. 2004).

# **EXHIBIT 6**

## EXHIBIT 6

**WITNESSES PLAINTIFF INTENDS TO CALL  
IN PERSON OR BY PRIOR SWORN TESTIMONY**

Plaintiff expects to call the following witnesses in person in their case in chief and/or in rebuttal during the trial. To the extent permitted by the Federal Rules of Evidence, Plaintiff also reserves the right to introduce the prior sworn testimony (*e.g.*, deposition testimony) of any witness named below.

**Fact Witnesses**

1. Scott Deng Apotex Inc. 380 Elgin Mills Road East Richmond Hill, Ontario Canada	9. Xue Ming Zhang Apotex Inc. 380 Elgin Mills Road East Richmond Hill, Ontario Canada
2. Ellen Gettenberg Apotex Corp. 2400 North Commerce Parkway, Suite 400 Weston, Florida U.S.A.	10. Harry Sacks Meda Pharmaceuticals Inc. 265 Davidson Avenue Somerset, New Jersey U.S.A.
3. Muhammad Hassan Apotex Inc. 380 Elgin Mills Road East Richmond Hill, Ontario Canada	11. Helmut Hettche Romerstrasse #43 63128 Dietzenbach Germany
4. Wan Jiang Apotex Inc. 380 Elgin Mills Road East Richmond Hill, Ontario Canada	12. R. Duane Sofia 82 Fairview Avenue Lancaster, Pennsylvania U.S.A.
5. Jeff Michaud Apotex Inc. 380 Elgin Mills Road East Richmond Hill, Ontario Canada	13. Corey Fishman Meda Pharmaceuticals Inc. 265 Davidson Avenue Somerset, New Jersey U.S.A.
6. Suganya Ramachandra Apotex Inc. 380 Elgin Mills Road East Richmond Hill, Ontario Canada	14. Naresh Chand 17804 Stoneridge Drive North Potomac, Maryland U.S.A.

7. Gina Sirianni Apotex Inc. 380 Elgin Mills Road East Richmond Hill, Ontario Canada	15. Istvan Szelenyi Händelstrasse #32 D-90571 Schwaig Germany
8. Cihua Yang Apotex Inc. 380 Elgin Mills Road East Richmond Hill, Ontario Canada	16. Juergen Engel Zentaris GmbH Weismueckerstrasse 50 60314 Frankfurt am Main Germany

**Expert Witnesses**

The subject matter of the testimony of the following expert witnesses is set forth in their respective expert reports served in this case and in their expert depositions taken in this case.

17. Byrn, Stephen R.  
Department of Industrial and Physical Pharmacy  
Purdue University  
West Lafayette, Indiana 47907

Expert medicinal chemist who will testify regarding the state of the art, the person of ordinary skill in the art, and validity issues. Dr. Byrn will testify regarding the definition of certain relevant scientific terms and explain certain relevant scientific concepts. Dr. Byrn will testify regarding the challenges of pharmacy and drug development, the proper meaning and interpretation of chemical and pharmaceutical terms, chemical structures and systems of chemical nomenclature, and general concepts in medicinal chemistry. Dr. Byrn's opinions are set forth in more detail in his expert reports and deposition testimony, and he reserves the right to supplement his reports after the Court's decisions on any pending motions and rulings on claim construction. Dr. Byrn also reserves the right to testify as to any opinions set forth in his reports and to respond to assertions made by Defendants' experts.

18. Meltzer, Eli O.  
Allergy & Asthma Medical Group and Research Center, A.P.C.  
9610 Granite Ridge Drive, Suite B  
San Diego, California 92123

Expert physician and clinician specializing in allergy, immunology, and respiratory disease who will testify regarding the state of the art, the person of ordinary skill in the art, and validity issues. Dr. Meltzer will testify regarding the definition of certain relevant medical terms and explain certain relevant medical concepts. Dr. Meltzer will testify regarding the proper meaning and interpretation of medical and scientific terms, and general concepts in allergy, immunology, and medicinal chemistry. Dr. Meltzer will testify regarding the treatment of various types of allergies in the past, in 1987, and today. Dr. Meltzer's opinions are set forth in more detail in his expert reports and deposition testimony, and he reserves the right to supplement his reports after the Court's decisions on any pending motions and rulings on claim construction. Dr. Meltzer also reserves the right to testify as to any opinions set forth in his reports and to respond to assertions made by Defendants' experts.



19. Dalby, Richard N.  
University of Maryland, Department of Pharmaceutical Sciences  
20 North Pine Street  
Baltimore, Maryland 21201

Expert pharmaceutical scientist who will testify regarding the state of the art, the person of ordinary skill in the art, and validity issues. Dr. Dalby will testify regarding the proper meaning and interpretation of relevant scientific terms and the challenges in developing nasal and other drug products. Dr. Dalby will testify regarding the challenges of pharmaceutical sciences in general and nasal pharmaceutical formulations and nasal delivery devices in particular. Dr. Dalby's opinions are set forth in more detail in his expert reports and deposition testimony, and he reserves the right to supplement his reports after the Court's decisions on any pending motions and rulings on claim construction. Dr. Dalby also reserves the right to testify as to any opinions set forth in his reports and to respond to assertions made by Defendants' experts.

20. Langer, Robert  
Institute Professor  
Massachusetts Institute of Technology
21. Donovan, Maureen  
University of Iowa  
College of Pharmacy  
115 S. Grand Ave.  
Iowa City, IA 52242
22. Schwartz, Howard J.  
6137 East Paseo Cimarron  
Tucson, AZ 85750

\* \* \*

Plaintiff reserves the right to call any additional witnesses necessitated by any new witness or evidence offered by Apotex or any of the Court's pretrial or trial rulings. In addition, Plaintiff reserves the right to call, either live or by deposition: (i) additional witnesses to provide foundational testimony should Defendants contest the authenticity or admissibility of any material proffered at trial; (ii) substitute witnesses for any identified witness whose employment or other relationship with a company changes such that he or she is no longer able, available or willing to testify on that company's behalf at trial; (iii) any witness identified by Defendants as required to rebut Defendants' case; and/or (iv) additional witnesses to respond to

issues raised after the submission of this list, such as the testimony of witnesses who have not yet been deposed. Plaintiff further reserves the right to introduce the deposition testimony of any witness who submitted an expert report or declaration on behalf of (or in support of) the Defendants, but who is not called live at trial. Because Plaintiff intends to call Dr. Sacks live at trial, designations and counter-designations of Dr. Sacks's deposition testimony are likely to be unnecessary and inappropriate. Nonetheless, out of an abundance of caution, Plaintiff has submitted counter-designations to Apotex's designations of Dr. Sacks's deposition testimony.

# **EXHIBIT 7**

EXHIBIT 7

**WITNESSES DEFENDANTS INTEND TO CALL  
IN PERSON OR BY PRIOR SWORN TESTIMONY**

Depending on the order of proof, Defendants do not anticipate calling any witnesses in person in their case in chief other than their expert witnesses identified below. The witnesses that Defendants would call as part of their case in chief are already listed by Plaintiff as among those that will be called in person or presented by prior sworn testimony in connection with Plaintiff's case in chief. To the extent that the witnesses listed by Plaintiff are not actually called in person to testify at trial, Apotex will present the prior sworn testimony (e.g., deposition testimony or testimony obtained pursuant to Letters of Request issued under the Hague Evidence Convention) of the following witnesses:

1. Dr. Istvan Szelenyi – a German witness
2. Mr. Helmut Hettche – a German witness
3. Dr. Jürgen Engel – a German witness
4. Dr. Naresh Chand
5. Dr. R. Duane Sofia
6. Mr. Corey Fishman – a current MedPointe employee
7. Dr. Richard Spivey – a current MedPointe employee
8. Dr. Harry Sacks – a current MedPointe employee
9. Mr. Jeffrey Hostler – a current MedPointe employee

The prior sworn testimony that Defendants would introduce as part of their case in chief is designated in Exhibit 13. The address for each of these witnesses has been previously identified by Plaintiff in Exhibit 6, *supra*.

## Expert Witnesses

The subject matter of the testimony of the following expert witnesses is set forth in their respective expert reports served in this case and in their expert depositions taken in this case.

1. Robert Langer, Ph.D  
Institute Professor  
Massachusetts Institute of Technology

Dr. Langer is a recognized expert in the pharmaceutical sciences and drug delivery systems with over 40 years of experience. Dr. Langer is expected to testify regarding the pharmaceutical sciences, the scope and content of the prior art, the person having ordinary skill in the art, the differences between the alleged invention(s) of the patent-in-suit and the prior art, whether the subject matter of the claims of the patent-in-suit are taught by one or more pieces of the prior art, the results of experiments conducted at Defendants' request regarding prior art azelastine formulations, and other issues within the scope of his expert reports and depositions. Dr. Langer's opinions are set forth in more detail in his expert reports and deposition testimony. Dr. Langer reserves the right to testify as to any opinions set forth in his reports and to respond to assertions made by the Plaintiff.

2. Maureen Donovan, Ph.D  
University of Iowa  
College of Pharmacy  
115 S. Grand Ave.  
Iowa City, IA 52242

Dr. Donovan is a recognized expert in the pharmaceutical sciences with 20 years of experience. Dr. Donovan is expected to testify regarding dosage forms for the eye and nose, formulation of such dosage forms, the scope and content of the prior art with regard to the patent-in-suit, the person having ordinary skill in the art, the differences between the alleged invention(s) of the patent-in-suit and the prior art, whether the subject matter of the claims of the patent-in-suit are taught by one or more pieces of the prior art. Dr. Donovan is also expected to testify regarding ophthalmic and nasal drugs and their formulation, issues of toxicity, and ciliotoxicity, general issues in the pharmaceutical sciences relevant to the claims of the patent in suit, and other issues within the scope of her expert reports and deposition. Dr. Donovan's opinions are set forth in more detail in her expert reports and deposition testimony. Dr. Donovan reserves the right to testify as to any opinions set forth in her reports and to respond to assertions made by the Plaintiff.

3. Dr. Howard J. Schwartz  
6137 East Paseo Cimarron  
Tucson, AZ 85750

Dr. Schwartz is a recognized expert in the fields of research and clinical allergy and immunology with over 35 years of experience. Dr. Schwartz is expected to testify about the anatomy and physiology of the nose, allergy and its treatment in general, medical conditions of the eye and nose, the activities and actions of antihistamines and other anti-allergy drugs, and methods of treating medical conditions of the eye and nose. Dr. Schwartz will also testify regarding experiments related to azelastine and its therapeutic activities, the scope and content of the prior art with regard to the patent-in-suit, the person having ordinary skill in the art, the differences between the alleged invention(s) of the patent-in-suit and the prior art, whether the subject matter of the claims of the patent-in-suit are taught by one or more pieces of the prior art, and other issues within the scope of his expert reports and deposition. Dr. Schwartz's opinions are set forth in more detail in his expert report and deposition testimony. Dr. Schwartz reserves the right to testify as to any opinions set forth in his reports and to respond to assertions made by the Plaintiff.

Defendants reserve the right to call any additional witnesses necessitated by any new witness or evidence offered by Meda or any of the Court's pretrial or trial rulings.. In addition, Defendants reserve the right to call, either live or by deposition, (i) additional witnesses to provide foundational testimony should Plaintiff contest the authenticity or admissibility of any material proffered at trial; (ii) substitute witnesses for any identified witness whose employment or other relationship with a company changes such that he or she is no longer able, available or willing to testify on that company's behalf at trial; (iii) any witness identified by Plaintiff as required to rebut Plaintiff's case; and/or (iv) additional witnesses to respond to issues raised after the submission of this list, such as the testimony of witnesses who have not yet been deposed. Defendants further reserves the right to introduce the deposition testimony of any witness who submitted an expert report or declaration on behalf of (or in support of) Plaintiff, but who is not called live at trial.

# **EXHIBIT 8**

EXHIBIT 8

**PLAINTIFF'S STATEMENT OF INTENDED PROOFS**

Plaintiff respectfully submits the following list of what it expects to prove at the upcoming trial.

In addition to the items identified below, Plaintiff intends to prove the matters identified in its Amended Complaint, interrogatory answers and in the expert reports, rebuttal reports and depositions of its expert witnesses. Plaintiff also intends to offer proof on the issues of fact and issues of law identified by Plaintiff and Defendants in this Pretrial Order. Plaintiff also intends to offer proof to rebut the items on which Defendants offer proof, and Plaintiff reserves the right to amend and supplement this statement and offer proofs in response to Defendants' pre-trial and trial activities, further discovery and Court rulings. As to issues on which Defendants have the burden of proof, Plaintiff reserves the right to supplement this statement after receipt of the statement of intended proofs Defendants proposed for the Pretrial Order. Regarding proof to be presented by expert testimony, Plaintiff incorporates by reference the expert reports of its experts.

The issue of infringement is the subject of a jointly submitted Stipulated Findings Of Fact. If the Court enters the Stipulated Findings Of Fact, Plaintiff will have met its burden of proving infringement of asserted Claims 4, 5, 7, 8 and 9 of the '194 patent and no infringement issues need be tried.

**I. INFRINGEMENT OF CLAIMS 4, 5, 7, 8 AND 9 OF THE '194 PATENT**

A. Absent entry of the Stipulated Findings Of Fact, Plaintiff will prove that Defendants' Generic Product as described in ANDA 77-954 meets each and every limitation of



Claims 4, 5, 7, 8 and 9 of the '194 patent, either literally or under the doctrine of equivalents, as those claims are properly construed.

B. Absent entry of the Stipulated Findings Of Fact, Plaintiff will prove that Defendants will commercially manufacture, use, offer to sell, sell or import the Generic Product, or induce or contribute to any such conduct, thereby infringing Claims 4, 5, 7, 8 and 9 of the '194 patent under 35 U.S.C. § 271(a), (b) and/or (c).

## **II. VALIDITY OF THE ASSERTED CLAIMS OF THE '194 PATENT**

Plaintiff intends, to the extent necessary, to introduce evidence to rebut each of Defendants' challenges to the validity of the asserted claims of the '194 patent. Defendants cannot prove by clear and convincing evidence that Claims 4, 5, 7, 8 and 9 of the '194 patent are anticipated or obvious and Plaintiff will submit evidence that confirms this conclusion.

## **III. ENFORCEABILITY OF THE '194 PATENT**

Plaintiff intends, to the extent necessary, to introduce evidence to rebut each of Defendants' challenges to the enforceability of the '194 patent. Defendants cannot prove by clear and convincing evidence that the '194 patent is unenforceable and Plaintiff will submit evidence that confirms this conclusion.

## **IV. MISUSE OF THE '194 PATENT**

Plaintiff intends, to the extent necessary, to introduce evidence to rebut each of Defendants' allegations of misuse of the '194 patent by Plaintiff. Defendants cannot prove by clear and convincing evidence that Plaintiff has misused the '194 patent and Plaintiff will submit evidence that confirms this conclusion.

## **V. EXCEPTIONAL CASE**

This case is exceptional under 35 U.S.C. § 285, entitling Plaintiff to recover its attorneys' fees from Defendants.

## **EXHIBIT 9**

EXHIBIT 9

**DEFENDANTS' STATEMENT OF INTENDED PROOFS**

Defendants respectfully submit the following list of what they expect to prove at the upcoming trial.

In addition to the items identified below and assuming that the Plaintiff and Defendants enter into a suitable stipulation on the issue of infringement, Defendants intend to prove all other matters identified in the Answer of Apotex Inc. and Apotex Corp. To Plaintiff's Amended Complaint, Affirmative Defenses And Counterclaims, their interrogatory answers and in the expert reports and depositions of their expert witnesses. Defendants also intend to offer proof on the issues of fact and issues of law identified by Plaintiff and Defendants in this Joint Pretrial Order. Defendants also intend to offer proof to rebut the items on which Plaintiff may offer proof to rebut the items on which Defendants offer proof. Regarding proof to be presented by expert testimony, Defendants incorporate by reference the expert reports of their expert witnesses.

**I      Infringement Of Claims 4, 5, 7, 8 And 9 Of The '194 Patent**

A.      The issue of infringement is the subject of a jointly submitted Stipulated Findings of Fact.

**II.     Invalidity Of The '194 Patent**

A.      The '194 patent is invalid as anticipated under 35 U.S.C. § 102.

B.      The subject matter as a whole defined in each of Claims 1-12 of the '194 patent would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

**III. Unenforceability Of The '194 Patent**

A. The '194 patent is unenforceable because the patentee engaged in inequitable conduct during prosecution of the applications underlying the '194 patent.

**IV. Misuse**

A. The patentee has engaged in misuse with respect to the '194 patent.

**V. Exceptional Case**

A. This is an exceptional case entitling Defendants to recover their attorneys fees from the Plaintiff.

# **EXHIBIT 10**

EXHIBIT 10

**PLAINTIFF'S MISCELLANEOUS ISSUES**

1. Jointly submitted Stipulated Findings Of Fact and infringement issues.
  2. Timing and format for resolving the parties' competing exceptional case claims.
  3. The need, timing and format for resolving a Plaintiff preliminary injunction motion that prevents Apotex from launching its proposed generic product before the Court issues its ruling on liability issues.
  4. Trial scheduling and witness availability issues.
  5. Submission of exhibits.
  6. Timing for oral *in limine* motions on Defendants' expert testimony.
  7. Jointly submitted Stipulation Regarding Name Change and Case Caption.
- (D.I. 132).

# **EXHIBIT 11**

EXHIBIT 11

**DEFENDANTS' MISCELLANEOUS ISSUES**

1. The production of the following documents previously requested during the deposition of Dr. Eli Meltzer, a MedPointe expert witness:

- a. Copies of the contracts and budgets relating to clinical studies conducted by Dr. Meltzer or the Allergy and Asthma Medical Group and Research Center for Carter-Wallace, Inc. and/or MedPointe relating to azelastine. See Deposition of Dr. Eli O. Meltzer ("Meltzer Dep."), 10/16/07, pp. 13-15.
- b. A copy of the agreement governing Dr. Meltzer's engagement as an expert witness in the above-referenced action. See Meltzer Dep., 10/16/07, pp. 24-25.
- c. A copy of Dr. Meltzer's notes that he used and referred to during the course of his deposition. See Meltzer Dep., 10/16/07, p. 183.

2. How the Court wishes to deal with the record of the testimony obtained from the German witnesses pursuant to the Letters of Request issued under the Hague Evidence Convention.

3. Plaintiff's December 31, 2007 production of two binders of German language documents under Fed. R. Civ. P. 26(e) and potential impact on Defendants' submissions in the Joint Pretrial Order.

4. The production of documents by Meda after the close of expert discovery and supplementation of expert reports.



## **EXHIBIT 12**

## EXHIBIT 12

**PLAINTIFF'S DEPOSITION DESIGNATIONS**

(with Defendants' objections and counter-designations)

**I. Rule 30(b)(6) Deposition of Defendant Apotex Inc. (Yang) – 5/16/07**  
**(including referenced exhibits)**

<b>Designation</b>	<b>Objections to Designations</b>	<b>Counter-Designations</b>	<b>Objections to Counter-Designations</b>	<b>Counter-Counter-Designations</b>
9:8-15				
18:13-18				
19:4-18				
20:20-21:16				
43:25-44:7				
44:20-23				
45:1-4				
45:6-15				
45:22-46:1				
46:3-49:5				
49:23-53:7				
53:17-55:24				
60:10-61:7				
63:13-65:21				
69:9-70:9				
75:6-25				
89:8-89:10				
89:19-21				
89:23-25				

**II. Rule 30(b)(6) Deposition of Defendant Apotex Inc. (Zhang) – 5/17/07**  
**(including referenced exhibits)**

<b>Designation</b>	<b>Objections to Designations</b>	<b>Counter-Designations</b>	<b>Objections to Counter-Designations</b>	<b>Counter-Counter-Designations</b>
7:16-19				
7:24-8:11				
15:1-15				
15:16-16:11				
16:17-17:6				
17:14-25				
19:22-20:15				
21:19-25				
24:22-25:7				
34:23-35:4				
36:25-37:19				
37:22-38:11				
38:16				
38:19-20				
39:8-10				
40:4-41:16				
41:20-24				

**III. Rule 30(b)(6) Deposition of Defendant Apotex Inc. (Jiang) – 4/26/07**  
**(including referenced exhibits)**

<b>Designation</b>	<b>Objections to Designations</b>	<b>Counter-Designations</b>	<b>Objections to Counter-Designations</b>	<b>Counter-Counter-Designations</b>
7:21-8:13				
15:7-16:1				
43:19-44:13				
44:15				

**IV. Rule 30(b)(6) Deposition of Defendant Apotex Inc. (Sirianni) – 5/18/07**  
**(including referenced exhibits)**

<b>Designation</b>	<b>Objections to Designations</b>	<b>Counter-Designations</b>	<b>Objections to Counter-Designations</b>	<b>Counter-Counter-Designations</b>
10:14-11:5				
17:12-18:7				
18:8-19:4				
19:11-21:7				
22:8-12				
26:9-27:5				
27:10-22				
34:15-25				
35:3-13				
35:22-36:17				
55:4-5				
56:6-10				
56:14-22				
57:2-4				
58:5-25				
59:8-21				
63:17-19				
65:2-16				
75:18-76:17				
76:23-77:21				
80:19-81:13				
97:16-98:7				
99:2-10				
100:11-21				
104:11-18				
104:24-105:7				
110:9-111:8				
111:14-112:5				
112:8-113:13				
114:8-13				
115:15-19				
115:24-116:12				

**V. Rule 30(b)(6) Deposition of Defendant Apotex Corp. (Gettenberg) – 6/21/07**  
**(including referenced exhibits)**

<b>Designation</b>	<b>Objections to Designations</b>	<b>Counter-Designations</b>	<b>Objections to Counter-Designations</b>	<b>Counter-Counter-Designations</b>
7:5-8				
7:12-8:1				
12:9-21				
21:9-25				
22:4-8				
22:11-17				
23:4-15				
23:19-24:10				
30:5-6				
33:13-20				
56:25-59:2				
59:14-60:4				
70:14-71:3				
71:7-14				
85:20-87:21				
96:6-8				
100:14-101:10				
104:14:105:17				

**VI. Deposition of Jeff Michaud – 4/27/07**  
**(including referenced exhibits)**

<b>Designation</b>	<b>Objections to Designations</b>	<b>Counter-Designations</b>	<b>Objections to Counter-Designations</b>	<b>Counter-Counter-Designations</b>
8:12-10:11				
14:6-13				
23:18-25:25				
28:21-25				
29:6-24				
35:11-23				
64:1-20				
67:13-17				
80:6-13				

**VII. Deposition of Scott Deng – 5/16/07**  
**(including referenced exhibits)**

<b>Designation</b>	<b>Objections to Designations</b>	<b>Counter-Designations</b>	<b>Objections to Counter-Designations</b>	<b>Counter-Counter-Designations</b>
8:18-21				
9:1-6				
9:22-25				
36:8-11				
40:17-23				
42:5-44:3				
45:2-5				
45:10				
87:22-24				
89:14-90:14				
91:7-14				
95:16-96:14				

**VIII. Deposition of Muhammad Hassan – 5/17/07**  
**(including referenced exhibits)**

<b>Designation</b>	<b>Objections to Designations</b>	<b>Counter-Designations</b>	<b>Objections to Counter-Designations</b>	<b>Counter-Counter-Designations</b>
8:3-6				
8:9-19				
28:4-29:16				
32:2-34:9				
35:14-36:2				
37:16-21				
38:8-40:1				
50:19-51:5				
51:22-52:4				
52:10-53:10				
53:13-54:22				
55:2-3				
55:15-17				
58:12-23				
60:21-25				

**IX. Deposition of Suganya Ramachandra – 4/26/07**  
**(including referenced exhibits)**

<b>Designation</b>	<b>Objections to Designations</b>	<b>Counter-Designations</b>	<b>Objections to Counter-Designations</b>	<b>Counter-Counter-Designations</b>
8:3-22				
32:5-25				
34:3-6				

## EXHIBIT 13

Exhibit 13



## EXHIBIT 13

**DEFENDANTS' DEPOSITION DESIGNATIONS****1. Deposition of Naresh Chand, Ph.D. taken April 18, 2007  
(including referenced exhibits)**

*MedPointe Healthcare, Inc. v. Apotex, Inc. et al*, Case No. 06-164-SLR  
U.S. District Court, District of Delaware

<b>Designation</b>	<b>Objections to Designations</b>	<b>Counter-Designations</b>	<b>Objections to Counter-Designations</b>	<b>Counter-Counter-Designations</b>
7:13-16				
9:19-21				
12:6-14	relevance			
17:2-20:17	relevance	20:21-22:12	Relevance	
22:14-23:20	relevance, incomplete testimony (add 23:21-23:22)	23:21-23:22		
24:10-25:19	relevance			
26:3-28:12	relevance, improper opinion testimony (27:20-28:6)			
28:13-38:14	relevance, mischaracterizes prior testimony (29:20-29:22); lack of foundation, improper opinion testimony (32:3- 32:22); vague (35:12-35:18); lack of foundation (38:3-38:14)	38:15-39:1	Relevance	
39:2-40:22				
42:15-43:21	vague, compound	43:22-44:14	relevance	
48:5-50:17	relevance, calls for legal conclusion,	42:4-42:14		

<b>Designation</b>	<b>Objections to Designations</b>	<b>Counter-Designations</b>	<b>Objections to Counter-Designations</b>	<b>Counter-Counter-Designations</b>
	privilege, colloquy (48:9-49:7)			
55:3-17		55:18-55:22; 56:5-56:13	Relevance (56:5-56:13)	
57:14-58:7				
59:10-63:12	vague (61:4-61:20); privilege, calls for legal conclusion (61:21-62:15)	63:13-64:1; 65:9-65:14		
67:13-69:7	relevance, (68:16-68:17), mischaracterizes prior testimony (68:18-68:20); vague (69:1-69:7)	69:8-69:16	Relevance	
70:3-73:12	mischaracterizes prior testimony (71:21-72:9)	73:13-73:22	Relevance	
74:16-77:13	improper opinion testimony, calls for speculation			
78:9-80:9	improper opinion testimony, calls for speculation	78:2-78:8; 80:11-81:15	Relevance (78:2-78:8)	
81:16-82:4	improper opinion testimony, calls for speculation			
83:2-92:8	relevance, hearsay (84:9-84:19); compound (84:20-85:3); lack of foundation, improper opinion testimony (85:8-85:16); colloquy (85:17-87:3); improper opinion testimony			

<b>Designation</b>	<b>Objections to Designations</b>	<b>Counter-Designations</b>	<b>Objections to Counter-Designations</b>	<b>Counter-Counter-Designations</b>
	(88:13-89:2); not testimony (89:3-89:10); relevance, hearsay (89:11-90:1); calls for legal conclusion (90:6-90:22); improper opinion testimony, calls for legal conclusion, calls for speculation (91:1-92:8)			
95:7-97:18	cumulative (95:7-96:8); mischaracterizes prior testimony (96:9-97:3); improper opinion testimony (97:4-97:18)	94:16-95:6	Relevance	
98:3-100:4	incomplete; compound (97:19-98:7)	97:19-98:2		
107:3-14	calls for speculation, improper opinion testimony	106:8-107:1; 107:15-108:1	Relevance (106:8-107:1); not testimony (106:15-106:16)	
108:2-110:17	vague (109:15-110:17)			
110:22-111:1	not testimony			
113:9-114:22	relevance, hearsay			
116:22-123:5	relevance, hearsay (116:22-118:22); calls for speculation, improper opinion testimony (122:3-122:12)			
123:6-126:9	relevance, hearsay; not			

<b>Designation</b>	<b>Objections to Designations</b>	<b>Counter-Designations</b>	<b>Objections to Counter-Designations</b>	<b>Counter-Counter-Designations</b>
	testimony (123:6-123:10); calls for speculation (125:12-125:14)			
128:13-129:14	relevance, hearsay (128:13-128:21)			
130:20-132:6		132:7-132:22		
135:6-139:8	relevance, hearsay, vague (135:12-135:20); mischaracterizes prior testimony (139:4-139:8)			
139:9-10	not testimony			
140:17-147:16	relevance, hearsay; calls for speculation (141:3-141:10); mischaracterizes prior testimony (141:11-142:6); calls for speculation (142:14-143:1); vague (145:1-145:4); calls for speculation, vague (147:7-147:16)	140:3-140:16		
152:16-156:10	relevance, hearsay, vague (153:3-153:13); vague (154:16-154:20); not testimony (155:6-155:10)			
157:11-167:19	relevance, hearsay, not testimony (157:11-157:14); calls for			

<b>Designation</b>	<b>Objections to Designations</b>	<b>Counter-Designations</b>	<b>Objections to Counter-Designations</b>	<b>Counter-Counter-Designations</b>
	speculation, improper opinion testimony (159:13-159:21); vague, relevance (164:2-165:9); competence (166:21-167:19)			
168:3-176:19	relevance, hearsay; not testimony (168:3-168:7); vague (172:18-172:20); speculation, improper opinion testimony (175:11-175:17); form of the question, speculation, improper opinion testimony (176:1-176:19)			
176:20-180:22	not testimony (176:20-177:1); relevance (177:12-177:17); vague (178:22-179:9); form of the question, speculation, lack of foundation, improper opinion testimony (180:3-180:22)			
181:1-189:20	not testimony (181:1-181:5); relevance (181:11-182:13); relevance (185:5-185:9); calls for	189:21-192:2		

Designation	Objections to Designations	Counter-Designations	Objections to Counter-Designations	Counter-Counter-Designations
	speculation, lack of foundation (186:11-186:21); mischaracterizes prior testimony (186:22-187:17); calls for speculation, lack of foundation, improper opinion testimony (189:12-189:20)			
192:7-195:21	mischaracterizes prior testimony (192:7-192:15); calls for speculation (192:16-193:15)			
196:10-199:18	vague (196:15-197:12); vague, calls for speculation, lack of foundation, improper opinion testimony (197:13-199:18)			
200:12-16	not testimony			
201:5-205:21				
206:3-233:22				
234:19-244:4				

**2. Deposition of R. Duane Sofia, Ph.D. taken June 14, 2007  
(including referenced exhibits)**

*MedPointe Healthcare, Inc. v. Apotex, Inc. et al*, Case No. 06-164-SLR  
U.S. District Court, District of Delaware

Designation	Objections to Designations	Counter-Designations	Objections to Counter-Designations	Counter-Counter-Designations
6:14-7:9				
7:10-8:15				

<b>Designation</b>	<b>Objections to Designations</b>	<b>Counter-Designations</b>	<b>Objections to Counter-Designations</b>	<b>Counter-Counter-Designations</b>
24:24-25:12		14:10-15:1 17:22-19:5 20:5-8 20:13-21:14 23:10-13 58:13-59:8		
26:10-27:19	incomplete question	26:9		
28:8-30:9				
30:23-32:4	mischaracterizes prior testimony (31:15-31:21)	36:24-37:20		
33:16-25				
34:24-35:11	incomplete answer	35:12-35:15		
38:8-14				
38:24-39:2				
41:10-44:11	calls for legal conclusion (43:11-44:4)	44:12-45:3		
46:19-47:3		47:16-49:19		
47:11-15				
51:2-20	vague	50:21-51:1; 51:21-52:4		
54:21-55:15	relevance			
66:1-6	incomplete question	65:22-25 66:7-9 69:12-71:20	Relevance (69:12-71:20)	
71:22-73:16	mischaracterizes prior testimony (72:14-715)			
73:17-75:1				
78:21-80:11	compound (78:21-24, 79:10-79:12)			
81:1-82:2				
104:6-105:3		107:2-109:25; 110:4-112:22 113:4-6 113:15-19 115:25-116:6		
125:16-126:1	hearsay, lack of foundation	124:16-125:8; 127:12-25		

<b>Designation</b>	<b>Objections to Designations</b>	<b>Counter-Designations</b>	<b>Objections to Counter-Designations</b>	<b>Counter-Counter-Designations</b>
		134:23-135:24		
139:14-140:23	hearsay			
141:14-24	hearsay and foundation			
143:1-144:3	relevance			
145:10-146:8	hearsay	151:1-152:2 155:14-22	Relevance (151:1-152:2)	
161:4-12		161:13-24		
167:2-172:1	lack of foundation, hearsay; relevance	172:2-172:14		
172:24-179:3	lack of foundation, hearsay, calls for a legal conclusion (178:24-179:3)			
180:5-182:21	hearsay, lack of foundation, calls for speculation (182:14-182:21)	183:8-183:18		
185:5-192:6	relevance, hearsay, lack of foundation, calls for speculation (187:25-188:4);			
192:13-15	not testimony			
192:21-199:19	hearsay, foundation, and mischaracterizes	199:25-200:13		

**3. Deposition of Corey Fishman taken April 13, 2007  
(including referenced exhibits)**

*MedPointe Healthcare, Inc. v. Apotex, Inc. et al*, Case No. 06-164-SLR  
U.S. District Court, District of Delaware

<b>Designation</b>	<b>Objections to Designations</b>	<b>Counter-Designations</b>	<b>Objections to Counter-Designations</b>	<b>Counter-Counter-Designations</b>
5:15-19				



<b>Designation</b>	<b>Objections to Designations</b>	<b>Counter-Designations</b>	<b>Objections to Counter-Designations</b>	<b>Counter-Counter-Designations</b>
6:6-12		8:23-10:12; 10:16-11:13; 11:18-11:23; 12:2-14:6		
14:7-13		14:14-16		
14:22-15:9				
16:6-14				
16:21-24		16:25-18-19:5		
19:23-20:4				
17:18-20	incomplete testimony			
22:18-23:13				
33:24-34:2				
34:5-16				
34:19-24				
37:25-38:13	lack of foundation, hearsay	35:23-37:24		
39:17-21				
42:17-43:9				
55:4-8				
55:13-19	vague			
55:24-56:10	vague			
61:3-10				
61:15-19	lack of foundation			
66:21-68:18				
69:21-70:2				
70:11-71:6				
71:11-14				
72:12-73:5	lack of foundation, hearsay (72:19-73:5)	73:6-73:11		
75:22-76:2	calls for legal conclusion			
76:15-77:7	hearsay, lack of foundation	77:8-77:17		
78:10-16	vague, calls for legal conclusion			
78:21-25	calls for legal conclusion,			

<b>Designation</b>	<b>Objections to Designations</b>	<b>Counter-Designations</b>	<b>Objections to Counter-Designations</b>	<b>Counter-Counter-Designations</b>
	assumes facts not in evidence			
80:11-81:8	lack of foundation, hearsay, calls for legal conclusion, relevance	79:14-80:5		
81:11-16	lack of foundation, hearsay			
82:6-18	lack of foundation, hearsay			
83:13-19		83:20-83:23		
83:24-84:23	lack of foundation, hearsay			
85:10-14		85:6-9		
85:17-20				
87:8-88:2	lack of foundation, hearsay			
88:17-22		88:11-16		
89:5-90:12	vague			
91:16-23	vague	91:24-92:3 94:5-21		
92:4-17	form of the question (92:4-92:9)			
93:18-24				
94:22-95:4	vague	95:5-95:9		
95:10-17	vague			
95:23-96:2				
96:14-20		96:21-23 97:18-97:21		
96:24-97:10				
97:22-98:2				
99:14-20				
101:19-102:2				
102:9-103:11		103:12-104:11		
105:7-106:2				

4. **Deposition of Dr. Richard Spivey taken July 3, 2007**  
**(including referenced exhibits)**

*MedPointe Healthcare, Inc. v. Apotex, Inc. et al*, Case No. 06-164-SLR  
U.S. District Court, District of Delaware

<b>Designation</b>	<b>Objections to Designations</b>	<b>Counter-Designations</b>	<b>Objections to Counter-Designations</b>	<b>Counter-Counter-Designations</b>
6:14-16				
6:22-7:7				
12:8-13				
19:2-14				
20:17-20				
21:2-3		21:15-21:22; 22:18-24:4 24:11-16 24:25-25:18 26:25-27:8 27:13-16 27:22-24 28:20-29:7 29:21-22		
31:7-14				
31:17-20	relevance			
34:10-35:10		32:2-23; 35:14-22 36:9-16 38:12-14 38:23-39:6 40:20-23 41:8-20 43:19-21 44:9-45:8 45:15-46:7 47:20-48:6 48:20-23 51:11-22 52:2-53:19 55:8-15 59:24-60:2 60:11-61:15 63:18-64:3 65:2-12		
49:25-50:3	relevance			
66:20-24				

<b>Designation</b>	<b>Objections to Designations</b>	<b>Counter-Designations</b>	<b>Objections to Counter-Designations</b>	<b>Counter-Counter-Designations</b>
67:8-14				
67:25-68:15	vague			
72:3-12				
77:8-20		76:24-77:7 77:21-23		
90:17-19	relevance	93:4-93:14		
97:4-8	calls for legal conclusion			
98:2-3	calls for legal conclusion			
98:10-21	calls for legal conclusion			
99:24-100:23	relevance, hearsay, assumes facts not in evidence, lack of foundation			
102:16-22	relevance			
122:14-21				
123:8-23				
123:25-124:6				
124:16-125:13	vague			
128:20-129:13				
129:16-130:4		125:15-126:4 127:24-128:10		
130:6-131:11				
131:16-132:12		132:16-19		
132:21-23				
132:25-133:10				
133:17-134:10				
136:22-137:9	relevance	112:13-20 114:25-115:17 119:7-11 137:11-25 138:5-10 138:24-139:13; 141:9-16 142:9-10 142:15-143:5 143:7-15 143:25-144:12 145:8-18		
146:3-147:3	lack of			

Designation	Objections to Designations	Counter-Designations	Objections to Counter-Designations	Counter-Counter-Designations
	foundation			
150:13-17	vague	150:18		
150:19-21	relevance	150:22-151:4		
151:24-152:14				
152:24-153:16		153:17-153:22		
160:2-161:4	hearsay, lack of foundation			
161:11-20	hearsay, lack foundation			
163:4-10	hearsay, lack foundation	162:20-163:3 164:11-164:15		
164:22-165:7	hearsay, lack foundation			
165:11-15	hearsay, lack foundation	165:8-10		
166:2-9	lack of foundation			
166:15-168:21	hearsay; lack of foundation	168:24-169:2 169:11-23		
171:14-25	lack of foundation, relevance			
172:11-173:4	lack of foundation	173:5-8		
173:9-18				
174:7-10	relevance			

**5. Deposition of Dr. Harry Sacks taken July 9, 2007  
(including referenced exhibits)**

*MedPointe Healthcare, Inc. v. Apotex, Inc. et al*, Case No. 06-164-SLR  
U.S. District Court, District of Delaware

Designation	Objections to Designations	Counter-Designations	Objections to Counter-Designations	Counter-Counter-Designations
6:4-9				
6:12-20		12:5-13:2 14:3-22 15:4-16 15:21-24 16:5-11		

<b>Designation</b>	<b>Objections to Designations</b>	<b>Counter-Designations</b>	<b>Objections to Counter-Designations</b>	<b>Counter-Counter-Designations</b>
		16:16-20 17:2-6 17:15-19:9 19:20-20:19 21:2-22:3 23:19-24:18 27:9-28:8 28:22-30:4 30:19-25 35:7-36:12 36:16-17		
31:12-15				
31:25-32:10				
34:22-35:6				
38:4-14				
39:15-40:8				
40:10-21		40:22-41:24		
44:15-17	relevance	44:25-45:17		
49:12-51:2	relevance	48:2-49:8		
51:5-15	relevance			
51:22-52:9	relevance	52:10-53:8		
66:5-67:16		67:17-23		
67:24-68:15		68:16-70:4		
85:4-86:19	vague, mischaracterizes prior testimony	81:14-85:3		
86:23-87:2		87:3-90:13		
126:21-128:24				
129:7-21	hearsay; relevance	150:5-11		
130:3-9	hearsay			
130:16-19				
131:17-133:17				
134:5-11				
134:20-135:13				
136:7-137:6		137:7-137:22		
137:24-138:21				
138:23-139:2				
139:4-8				
139:10-18				
139:20-140:5				
140:12-20				

Designation	Objections to Designations	Counter-Designations	Objections to Counter-Designations	Counter-Counter-Designations
140:22-142:18		142:19-142:21		
142:23-143:7		143:8-143:12		
143:21-149:17		61:18-66:4 70:16-21 73:13-78:23 79:2-80:7 80:14-81:13 91:10-14 91:23-93:12 94:17-95:15		
150:13-152:21		152:25-153:3		
153:5-13		153:14-153:18		
154:5-156:8	relevance, calls for speculation (154:5-155:12); relevance, lack of foundation (155:21-156:8)			
156:21-157:7				
157:9-10				
157:12-161:4	relevance, lack of foundation, hearsay			
161:23-163:22	relevance, lack of foundation, and hearsay			
174:2-16	relevance	176:24-177:8; 177:19-180:11		
191:22-193:14				
194:18-195:12		195:14-196:3; 196:15-200:5		
200:6-201:25				
202:21-206:6		207:20-209:20		
206:10-207:3	relevance			

**6. Deposition of Jeffrey Hostler taken August 1, 2007  
(including referenced exhibits)**

*MedPointe Healthcare, Inc. v. Apotex, Inc. et al*, Case No. 06-164-SLR  
U.S. District Court, District of Delaware

<b>Designation</b>	<b>Objections to Designations</b>	<b>Counter-Designations</b>	<b>Objections to Counter-Designations</b>	<b>Counter-Counter-Designations</b>
6:3-5				
6:13-7:10				
9:5-8		8:10-8:22; 9:13-11:14; 11:18-11:24		
13:15-23		12:11-13:10		
14:13-21		17:20-18:13		
14:22-25				
15:4-16:17				
16:21-23				
19:24-20:1				
20:7				
20:13-14				
21:5-11				
21:15-19				
21:22-25				
22:12-17		22:18-22:22; 23:3-23:15		
30:5-10				
30:13-31:5		31:24-32:3		
32:10-15		32:16-33:2; 34:7-34:11; 34:22-35:6		
37:12-19		37:20-38:1		
38:2-8				
39:12-15				
40:2-6				
40:10-16				
40:21-23		40:24-41:5		
41:6-11				
41:22-42:4		42:7-42:8		
44:2-8				
44:12				
44:21-45:14		52:11-53:7 54:15-23 57:13-23		
46:1-14		46:24-49:2		
51:8-15				
78:19-23	outside the scope of the deposition	78:5-18		
79:2-6	outside the scope of the deposition			



Designation	Objections to Designations	Counter-Designations	Objections to Counter-Designations	Counter-Counter-Designations
86:5-22	outside the scope of the deposition	86:23-87:15		

7. **Hague Evidence Convention Testimony of Dr. Istvan Szelenyi, taken September 20, 2007 Pursuant to Letters of Request issued in *MedPointe Healthcare, Inc. v. Apotex, Inc. et al*, Case No. 06-164-SLR**  
**U.S. District Court, District of Delaware (including referenced exhibits)**

Subject to further guidance from the Court (see Miscellaneous Issues, *supra*), Defendants designate the following testimony obtained from Dr. Istvan Szelenyi in connection with the Letters of Request issued pursuant to the Hague Evidence Convention as well as the specific questions identified in the Letter of Request for which testimony was obtained under oath:

Designation	Objections to Designations	Counter-Designations	Objections to Counter-Designations	Counter-Counter-Designations
Question A, p. 4 – p.6, 4 <sup>th</sup> para.				
Question A, p.6	improper translation (A4, p. 6, "to")	Question A, Number 6, p.6 - p.7 Question of Defendants' Attorney, p. 7		
Question C2, p. 10				
Question of Defendants' Attorney, p. 10 – p. 11, 1 <sup>st</sup> para.				
Question D1, p. 11				
Question D2, p. 11				
Question D4, p. 12 – p.12, 2 <sup>nd</sup> para.	incomplete answer	Question D4, p. 12 – p.12, 3 <sup>rd</sup> para.	Nonresponsive	
Question D5, p.	improper			

<b>Designation</b>	<b>Objections to Designations</b>	<b>Counter-Designations</b>	<b>Objections to Counter-Designations</b>	<b>Counter-Counter-Designations</b>
13 – p.14, 4 <sup>th</sup> para.	translation (D5, p. 14, ¶ 3 "ketotives")			
Question D6, p. 14				
Question D7, p. 14	form of the question, relevance			
Question D9, p. 15		Question D19, p. 17	Relevance	
Question D12, p. 16	relevance			
Question of Defendants' Attorney, p. 16	relevance			
Question D14, p. 17				
Question D24, p. 19				
Question D30, p. 21				
Question D31, p. 22				
Question D41, p. 23		Question D28, p. 20 Question D29, p. 20 - p. 21 Question of Defendants' Attorney, p. 21 Questions D32-34, p. 22 Question D42, p. 24		
Questions E1 & E2, p. 24				
Question E6, p. 25 – p. 26, 1 <sup>st</sup> para.				
Question asked by Defendants' Attorney, p. 26				
Comment of				

Designation	Objections to Designations	Counter-Designations	Objections to Counter-Designations	Counter-Counter-Designations
Defendants' Attorney, p. 26				
Further Questions of Defendants' Attorney, p. 27 – p. 27, 2 <sup>nd</sup> para.	incomplete answer	Further Questions of Defendants' Attorney, p. 27 – p.27, 1st, 3rd, 4th and 5th paras.		
Further Questions of Defendants' Attorney, p. 28, 1 <sup>st</sup> & 4 <sup>th</sup> para.	incomplete answer	Further Questions of Defendants' Attorney, p. 28, 2nd & 3rd para.		
Other Questions, p. 29				
Question of Defendants' Attorney, p. 29				
Question F1, p. 30		To the questions asked, namely to question 2, p. 30 - p. 31, 3rd para.	Nonresponsive	
Question H1, p. 31				
Question K, p. 33, 1 <sup>st</sup> para.	incomplete answer	Question K, p.32, p. 33 (2nd and 3rd paras).	Vague	

**8. Hague Evidence Convention Testimony of Dr. Helmut Hettche, taken December 10, 2007 Pursuant to Letters of Request issued in *MedPointe Healthcare, Inc. v. Apotex, Inc. et al*, Case No. 06-164-SLR  
U.S. District Court, District of Delaware (including referenced exhibits)**

Subject to further guidance from the Court (see Miscellaneous Issues, *supra*), Defendants designate the following testimony obtained from Dr. Helmut Hettche in connection with the Letters of Request issued pursuant to the Hague Evidence Convention as well as the specific questions identified in the Letter of Request for which testimony was obtained under oath:

<b>Designation</b>	<b>Objections to Designations</b>	<b>Counter-Designations</b>	<b>Objections to Counter-Designations</b>	<b>Counter-Counter-Designations</b>
Question B4, p. 2				
Question E8, pp. 9-10				
Question F1 (3 <sup>rd</sup> question), pp. 11-12		Question F1 (2 <sup>nd</sup> question), p. 11		
Question F3, pp. 12-13				
Question F6, p. 13	relevance			
Question F8, pp. 13-14	relevance			
Questions F13 & F14, pp. 14-15				
Question F16, p. 16				
Questions G3 & G4, pp. 16-17	relevance			
Question G6 (2 <sup>nd</sup> question), p. 17	relevance, lack of foundation	Question G5, p. 17 Question G6 (1 <sup>st</sup> question), p. 17		
Question G15, p. 19				
Question H3 (1 <sup>st</sup> question), p. 20	mischaracterizes prior testimony	Question H5 (2 <sup>nd</sup> question), p. 21 Question H5 (3 <sup>rd</sup> question), p. 21	Beyond the scope of the designated testimony	
Question H3 (2 <sup>nd</sup> question), p. 21				
Question H8, pp. 22-23	calls for legal conclusion			
Question H9 (2 <sup>nd</sup> question), p. 23	calls for legal conclusion			
Question I5, p. 24				
Question I13, p. 26		Question I10, p. 25 Question I11, p. 25		
Question I15, p. 26				

<b>Designation</b>	<b>Objections to Designations</b>	<b>Counter-Designations</b>	<b>Objections to Counter-Designations</b>	<b>Counter-Counter-Designations</b>
Question I18, p. 27	relevance			
Question I19, p. 27				
Question I20 (2 <sup>nd</sup> question), p. 27		Question I20 (1st question), p. 27		
Question I21 & I22, p. 28	mischaracterizes the document	Question I23, p. 28		
Question J4, p. 30	lack of foundation foundation			
Question L9 (2 <sup>nd</sup> question), p. 34	relevance	Question L9 (1st question), p. 33		
Question O4 (2nd question), p. 36	mischaracterizes prior testimony	Question O4 (1st question), p. 36		
Question O6, p. 37				
Question S1 (3 <sup>rd</sup> question), pp. 39-40	lack of foundation, calls for opinion testimony	Question E10, p. 10 Question R1, pp. 38-39		
Question U1 (2 <sup>nd</sup> question), pp. 40-41	relevance			
Questions Y1 thru Y9, pp. 41-43				
Questions Y11 thru Y16, pp. 41-43				
Question DD1, p. 46				
Question DD2, p. 46	not testimony			
Question DD6, p. 46	lack of foundation			
Question DD8, p. 46				
Question DD10, p. 46	lack of foundation			
Question DD16, p. 46	lack of foundation			

<b>Designation</b>	<b>Objections to Designations</b>	<b>Counter-Designations</b>	<b>Objections to Counter-Designations</b>	<b>Counter-Counter-Designations</b>
Question EE3, pp. 47-48	lack of foundation			
Question EE4, pp. 47-48	lack foundation, calls for a legal conclusion			
Questions EE9 thru EE10, pp. 49-51	lack of foundation, calls for opinion testimony			
Question JJ4, pp. 54-55	lack of foundation			
Question NN4, p. 57		Question NN1 (2nd question), pp. 56 and 57	Vague	

**9. Hague Evidence Convention Testimony of Dr. Jürgen Engel, taken January 18, 2008 Pursuant to Letters of Request issued in *MedPointe Healthcare, Inc. v. Apotex, Inc. et al*, Case No. 06-164-SLR  
U.S. District Court, District of Delaware (including referenced exhibits)**

Subject to further guidance from the Court (see Miscellaneous Issues, *supra*), Defendants designate the following testimony obtained from Dr. Jürgen Engel in connection with the Letters of Request issued pursuant to the Hague Evidence Convention as well as the specific questions identified in the Letter of Request for which testimony was obtained under oath:

<b>Designation</b>	<b>Objections to Designations</b>	<b>Counter-Designations</b>	<b>Objections to Counter-Designations</b>	<b>Counter-Counter-Designations</b>
Question B, p. 3				
Question B7, p. 4	incomplete answer	Question B7, p. 3		
Question E1, p. 6				
Questions H1 & H2, pp. 8-9		Question H1, p. 7, final line - p. 8, all paras. not designated by Defendants.	Not testimony	

<b>Designation</b>	<b>Objections to Designations</b>	<b>Counter-Designations</b>	<b>Objections to Counter-Designations</b>	<b>Counter-Counter-Designations</b>
Questions H5, H6 & H7, pp. 9-10	assumes facts not in evidence, calls for speculation, lack of foundation			
Question J3, pp. 15-16	incomplete answer	Question J3, p. 15, all paragraphs not designated by Defendants.	Counterdesignation not clear; some not testimony	
Question K8, p. 22				
Question M1, pp. 22-23				
Question M5, p. 24	incomplete answer	Question M5, clause 2, p. 23 - p. 24, all paragraphs not designated by Defendants. Question M6, p. 24	Not testimony	
Question R1, p. 26	relevance			
Question R2, p. 26	relevance	Question Q2, p. 25 Question Q4, p. 25		

# **EXHIBIT 14**



EXHIBIT 14

**PLAINTIFF'S LIST OF TRIAL EXHIBITS**

Attached is a list of exhibits that Plaintiff intends to offer at trial.

**MedPointe Healthcare, Inc. v. Apotex, Inc., et al.**  
 Civil Action No. 1:2006-cv-00164  
 Plaintiff's Trial Exhibits

PTX	Description	Bates Range	PDX	Admission		Date Admitted
				No Obj.	Objection Basis	
1	Certified Copy of US Patent No. 5,164,194					
2	Prosecution History for US Patent No. 5,164,194	MPAT 000007-000186				
3	2007-04-13 Deposition of Corey Fishman					
4	2007-04-18 Deposition of Naresh Chand					
5	2007-04-26 Deposition of Wan Jiang					
6	2007-04-26 Deposition of Suganya Ramachandra					
7	2007-04-27 Deposition of Jeff Michaud					
8	2007-05-16 Deposition of Cihua Yang					
9	2007-05-16 Deposition of Scott Deng					
10	2007-05-17 Deposition of Muhammad Hassan					
11	2007-05-17 Deposition of Xue Ming Zhang					
12	2007-05-18 Deposition of Gina Louise Sirianni					
13	2007-06-14 Deposition of R. Duane Sofia					
14	2007-06-21 Deposition of Ellen Gettenberg					
15	2007-07-03 Deposition of Richard Spivey					
16	2007-07-09 Deposition of Harry Sacks					
17	2007-07-09 Deposition of Elizabeth French					
18	2007-08-01 Deposition of Jeffrey Hostler					
19	2007-10-10 Deposition of Maureen Donovan					
20	2007-10-12 Deposition of Stephen Bym					
21	2007-10-16 Deposition of Eli Meltzer					
22	2007-10-17 Deposition of Howard Schwartz					
23	2007-10-19 Deposition of Richard Dalby					
24	2007-10-24 Deposition of Robert Langer					
25	2008-01-04 Deposition of Robert Langer					
26	N. Chand, "Inhibition of Allergic and Nonallergic Histamine Secretion by Azelastine, Its Putative Metabolites and Analogs in Rat Peritoneal Mast Cells and Rabbit Mixed Leukocytes (Basophils)," Wallace Laboratories, Pharmacology, PH-84-6, February 27, 1984 (Plaintiff's Deposition Exhibit 1).	ASN 003646-003665	1			
27	Report No. PH-86-2	ASN 003727-003744	2			
28	Notice of Deposition: Docket No. 66		3			
29	Drug Master File: Azelastine Hydrochloride-Datto	A 004986-005050	4			
30	Azelastine Hydrochloride 137 mg/mL: Quality Overall Summary	A 001025-001052	5			

**MedPointe Healthcare, Inc. v. Apotex, Inc., et al.**  
 Civil Action No. 1:2006-cv-00164  
 Plaintiffs Trial Exhibits

PTX	Description	Bates Range	PDX	Admission		Date Admitted
				No Obj.	Objection Basis	
31	Lab Notebook pages (Book No. 12040048)	A 002543-002550	6			
32	Lab Notebook pages (Book No. 12040113)	A 002632-002677	7			
33	Lab Notebook pages (Book No. 12040102)	A 002472-002517	8			
34	Lab Notebook pages (Book No. 12050016)	A 002422-002435	9			
35	Lab Notebook pages (Book No. 12050016)	A 002384-002421	10			
36	Lab Notebook pages (Book No. 12050065)	A 002342-002347	11			
37	Lab Notebook pages (Book No. 10050006)	A 004243-004255	12			
38	Lab Notebook pages (Book No. 10050006)	A 003311-003314	13			
39	Lab Notebook pages (Book No. 10050006)	A 004501-004530	14			
40	Lab Notebook pages (Book No. 10050054)	A 004548-004556	15			
41	Lab Notebook pages (Book No. 10050054)	A 004673-004690	16			
42	Test Methods	A 001990-002071	17			
43	Validation Summary of Test Method # AZEL-NASO-10-RH For Assay Per Spray of Azelastine Hydrochloride Nasal Spray	A 002245-002282	18			
44	Labeling Text Draft	A 000956-000967	19			
45	Pharmaceutical Development, Book No. 10040031	A 004866-004878	20			
46	Laboratory Notebook, Book No. 10050036	A 004704-004838	21			
47	Laboratory Notebook, Book No. 10050036	A 004324-004449	22			
48	Pharmaceutical Development, Book No. 10050012	A 004879-004919	23			
49	Pharmaceutical Development, Book No. 10050012	A 004531-004547	24			
50	Laboratory Notebook, Book No. 10050036	A 004697-004703	25			
51	Labeling Text Draft	A 000968-000980	27			
52	Azelastine Hydrochloride Nasal Spray 137mcg: Manufacture	A 001109	28			
53	Formulation Development Department: Product Development Report	A 001099-001107	29			
54	Raw Material Specification and Certificate of Analysis	A 001705-001707	30			
55	Pharmaceutical Development, Book No. 10040015	A 003766-003782	31			
56	Pharmaceutical Development, Book No. 10040012	A 003963-004054	32			
57	Research and Development (RH)	A 005199-005216	34			
58	Apotex Incorporated	A 005217-005234	35			
59	RDD-Product Development, Liquids RH	A 005175-005198	36			
60	Astelin Product Insert					
61	Pharmaceutical Development, Book No. 10040045	A 003688-003707	38			
62	Pharmaceutical Development, Book No. 10040074	A 003708-003709	39			
63	Pharmaceutical Development, Book No. 10040074	A 003755-003765	40			

**MedPointe Healthcare, Inc. v. Apotex, Inc., et al.**  
 Civil Action No. 1:2006-cv-00164  
 Plaintiffs Trial Exhibits

PTX	Description	Bates Range	PDX	Admission		Date Admitted
				No Obj.	Objection Basis	
64	Pharmaceutical Development, Book No. 10040074	A 003783-003796	41			
65	Pharmaceutical Development, Book No. 10040074	A 003810-003813	42			
66	Pharmaceutical Development, Book No. 10040074	A 003814-003819	43			
67	Pharmaceutical Development, Book No. 10040074	A 003820-003822	44			
68	Pharmaceutical Development, Book No. 10040074	A 003823-003826	45			
69	Pharmaceutical Development, Book No. 10040074	A 003831-003840	46			
70	Pharmaceutical Development, Book No. 10040093	A 003945-003951	47			
71	Pharmaceutical Development, Book No. 10040074	A 003797-003809	48			
72	Pharmaceutical Development, Book No. 10040025	A 004230-004233	49			
73	Pharmaceutical Development, Book No. 10050045	A 004317-004323	50			
74	Azelastine Hydrochloride Nasal Spray 137mcg: Components of the Drug Product (Excipients)	A 001064	51			
75	Azelastine Hydrochloride Nasal Spray 137mcg: Comparison of Generic Drug and Reference Listed Drug	A 000948	52			
76	Email to Yasmin Sethna et al. from Anita Hui - February 25, 2005	A 005264	53			
77	Fax to Kaidesh Shnoff from Angela Payne - July 3, 2006	A 005063-005065	54			
78	Email to Tammy McIntire et al. from Bob Billings - July 7, 2004	A 005235	55			
79	Email to Dorra Jordanou et al. from Kami-Sue Foo Loi - September 26, 2005	A 005236-005237	56			
80	E-mail to Barry Sherman from Gina Sirianni - January 24, 2006	A 005071	58			
81	CNA2 Azelastine HCl log	A 005048-005050	59			
82	Azelastine 137mcg Nasal Spray Info	A 004944	60			
83	Azelastine Nasal Spray International Product Target Charts	A 004945-004946	62			
84	Exec Summary - Azelastine Nasal Spray - F to F Forec	A 005051-005059	63			
85	Levocabastine HCl Product Data	A 000894	64			
86	Clemastine	A 000890-000893	65			
87	Paragraph IV Certification Statement	A 001016	66			
88	Notice of Deposition: Docket No. 67		67			
89	First pages of ANDA	A 000942-000944	68			
90	Letter of authorization for agent	A 001023	69			
91	Azelastine Hydrochloride Nasal Spray 137mcg: Listed Drug Labeling - Prescribing Information	A 000989-001000	70			
92	Receipt of ANDA		71			
93	Paragraph IV Certification - US Patent 5,164,194	A 005060-005062	72			

**MedPointe Healthcare, Inc. v. Apotex, Inc., et al.**  
 Civil Action No. 1:2006-cv-00164  
 Plaintiffs Trial Exhibits

PTX	Description	Bates Range	PDX	Admission		Date Admitted
				No Obj.	Objection Basis	
94	PST Meeting Minutes - July 7, 2004	A 006185-006206	73			
95	PST Meeting Slideshow; Pre-PST Meeting Agenda; Newport Global Horizon website printout	A 006208-006219	74			
96	Donovan Expert Report		77			
97	Byrn Expert Report		78			
98	Kimura, "Effects of Chemical Agents on Ciliated Tracheal Epithelium"	AS-MEDA 000430-000442	79			
99	Fukuda, "Influence of 1-(2-Ethoxyethyl)-2-(4-methyl-1-homopiperazinyl)benzimidazole Difumarate (KB 2413), a New Antiallergic, on Ciliary Movement"	AS-MEDA 010111-010113	80			
100	van de Donk, "The Effects of Drugs on Ciliary Motility"	MPAT 000523-000531	81			
101	Hermens, "The Influence of Drugs on Nasal Ciliary Movement"	A 000574-000578	82			
102	Donovan, "Drug Effects on in vivo nasal clearance in rats"		83			
103	U.S. Patent No. 3,813,384	A 000133-000138	84			
104	U.S. Patent No. 4,704,387	A 000564-000569	85			
105	Vademecum, for Pharmacists	AS-MEDA 000624-000629	86			
106	Gundrum, "Experimental Investigations on Action of Antihistaminic Nasal Solutions"		87			
107	Schwartz Expert Report		90			
108	Schwartz Curriculum Vitae		91			
109	Prosecution History for US Patent No. 4,704,387	A 005693-005787	93			
110	Secher, "Significance of H1 and H2 receptors in the human nose: rationale for topical use of combined antihistamine preparations"		94			
111	Remington's Pharmaceutical Sciences (pp. 1124-1132. 1633, 1646, 1662)		95			
112	Schwartz, "The Efficacy and Safety of Nedocromil Sodium 1% Nasal Solution in the Treatment of Ragweed Seasonal Allergic Rhinitis"		96			
113	Schwartz, "Cromolyn Sodium and Its Effects on Nasal Disease"		97			
114	Corren, "Effectiveness of Azelastine Nasal Spray Compared with Oral Cetirizine in Patients with Seasonal Allergic Rhinitis"		98			



**MedPointe Healthcare, Inc. v. Apotex, Inc., et al.**  
 Civil Action No. 1:2006-cv-00164  
 Plaintiffs Trial Exhibits

PTX	Description	Bates Range	PDX	Admission		Date Admitted
				No Obj.	Objection Basis	
115	Kirkegaard, "Inhibition of Histamine-Induced Nasal Symptoms by the H1 Antihistamine Chlorpheniramine Maleate"	A 000386-000395	99			
116	U.S. Pharmacopeia (p. 1655)	AS-MEDA 002129	100			
117	Allergy: Principles and Practice, Third Edition (pp. 1269-1283)		102			
118	Schwartz, "A Multicentered trial of nedocromil sodium, 1% nasal solution, compared with cromolyn sodium and placebo in ragweed seasonal allergic rhinitis"		103			
119	Busse, "New directions and dimensions in the treatment of allergic rhinitis"		104			
120	Electronic Orange Book Query re Diphenhydramine		105			
121	Kirkegaard, "Effect of the H1 Antihistamine Chlorpheniramine Maleate on Histamine-Induced Symptoms in the Human Conjunctiva"	A 000366-000371	107			
122	Zechei, "Pharmacological and Toxicological Properties of Azelastine, a Novel Antiallergic Agent"	A 005102-005111	109			
123	Chand, "Inhibition of acute lung anaphylaxis by aerosolized azelastine in guinea pigs sensitized by three different procedures"		112			
124	Kemp, "A dose-response study of the bronchodilator action of azelastine in asthma"	A 004951-004957	113			
125	Pecoud, "Effect of a new selective H1 receptor antagonist (Levocabastine) in a nasal and conjunctival provocation test"	A 000482-000486	114			
126	Lee, "Meta-analysis of Azelastine Nasal Spray for the Treatment of Allergic Rhinitis"	ASC 000231-000238	115			
127	Portnoy, "Evidence Based Strategies for Treatment of Allergic Rhinitis"		116			
128	Ratner, "Randomized double-blind trial of azelastine nasal spray plus fluticasone nasal spray compared to either agent alone in patients with allergy to Texas Mountain Cedar" (Abstract)		117			
129	Schwartz Revised Expert Rebuttal Report		118			
130	Langer Expert Report		120			
131	Langer Supplemental Expert Report		121			
132	U.S. Patent No 4,767,402		123			
133	Langer, "New Methods of Drug Delivery"		124			

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PTX	Description	Bates Range	PDX	Admission		Date Admitted
				No Obj.	Objection Basis	
134	Langer, "Drug Delivery Modalities" (Chapter of Principles of Pharmacology)		125			
135	U.S. Patent No. 6,060,082		126			
136	German Patent No. 21 64 058		133			
136A	English Translation of German Patent No. 21 64 058					
137	Ansel, "Introduction to Pharmaceutical Dosage Forms" (pp. 246-286)		137			
138	U.S. Patent No. 4,841,047.	A 000735-000753	138			
139	Byrn Opposition Expert Report					
140	Dalby Expert Report					
141	Dalby Opposition Expert Report					
142	Meltzer Expert Report					
143	Meltzer Opposition Expert Report					
144	Schwartz Rebuttal Expert Report					
145	Curriculum Vitae of Dr. Stephen R. Byrn					
146	Remington's Pharmaceutical Sciences, 17th Edition. Ed. Gennaro. Easton: Mack Publishing Company, 1985. 82-83, 1278, 1418-19, 1494.					
147	Apotex's Responses to Plaintiff's First Set of Requests for Admission					
148	The United States Pharmacopeia, 16th Edition. Rockville: United States Pharmacopeial Convention. 1985. 10.					
149	The Merck Index, 14th Edition. Ed. O'Neil. Whitehouse Station: Merck Research Laboratories, 2006. 153.					
150	Hawley's Condensed Chemical Dictionary, 12th Edition. Ed. Lewis. New York: Van Nostrand Reinhold Company. 1993. 354.					
151	McGraw-Hill Dictionary of Chemical Terms. Ed. Parker. New York: McGraw-Hill, 1985. 44.					
152	Chart Illustrating Infringement - Byrn Report Exhibit					
153	List of Previous Expert Testimony					
154	List of Documents Reviewed by Stephen R. Byrn					
155	Results of Phase I Study of E-0659	ATI 002091-002102				

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PTX	Description	Bates Range	PDX	Admission		Date Admitted
				No Obj.	Objection Basis	
156	Ollier, S. "The Effect of Single and Multiple Dose Therapy with Azelastine on the Immediate Asthmatic Response to Allergen Provocation Testing." J. Allergy Clin. Immunology. Vol 78, 1986: 358-64.	A 006422-006428				
157	Remington's Pharmaceutical Sciences, 17th Edition. Ed. Gennaro. Easton: Mack Publishing Company, 1985. 63, 441, 1417, 1492-1517, 1607-1608, 1631, 1633, 1644-61.					
158	H.J.M. van de Donk, J. Zuidema and F.W.H.M. Merkus, "The effects of nasal drops on the ciliary beat frequency of chicken embryo tracheas." Rhinology, Vol. 19, 1981: 215-230.	A 000309-000324				
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160	Gorenberg, D. "Rhinitis Medicamentosa." The Western Journal of Medicine. Vol. 131, 1979: 313-14.					
161	Management of the Allergic Patient: A Text for the Primary Care Physician. Ed. Lieberman, Crawford. New York: Appleton-Century-Crofts, 1982. 155-68.					
162	Johnson, SR. "Recent Progress in the Computational Prediction of Aqueous Solubility and Absorption." The AAPS Journal. Vol. 8, 2006: E27-E40.					
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165	Chand, N. "Inhibition of Passive Cutaneous Anaphylaxis (PCA) by Azelastine: Dissociation of its Antiallergic Activities from Antihistaminic and Antiserotonin Properties." Int. J. Immunopharmac. Vol. 7, 1985: 833-38.	A 004966-004971				
166	Chand, N. "Inhibition of Leukotriene (SRS-A)-Mediated Acute Lung Anaphylaxis by Azelastine in Guinea Pigs." Allergy. Vol. 41, 1986: 473-78.					



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PTX	Description	Bates Range	PDX	Admission		Date Admitted
				No Obj.	Objection Basis	
167	Jones, WR. "Quantitative Evaluation of Surface Anesthetics in Albino Mice." J. Pharm Sci. Vol 52. 1963: 500-01.					
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170	L.H. Hamilton, "Effect of Topical Decongestants on Nasal Airway Resistance," Current Therapeutic Research, Vol. 24, No. 3, pp. 261-268 (August 1978).	A 000213-000221				
171	Kerp, L. "Testing of the Antihistamine HS 592* on Histamine-Induced and "48/80"-Induced Erythema and in Patients with Immediate Allergic Reactions." Med. Welt. Vol. 51, 1966: 2794-98.					
171A	English Translation of Kerp, L. "Testing of the Antihistamine HS 592* on Histamine-Induced and "48/80"-Induced Erythema and in Patients with Immediate Allergic Reactions." Med. Welt. Vol. 51, 1966: 2794-98.					
172	Physicians' Desk Reference, 41st Edition. Ed. Huff. Oradell: Medical Economics Company. Inc., 1987. 961, 1275, 2106.					
173	Web Printout of Novartis: Vibrocil Information					
174	A.A. Kassem, E. Nour El-din, N.M. Murse, A. Abd Elbary and N. Foda, "Formulation and Stabilization of Antazoline Hydrochloride Nasal Drops," Bulletin of the Faculty of Pharmacy, Vol. 15, No. 2, pp. 161-175 (1976).	A 000175-000193				
175	R. Kersten, "Ophthalmic Drugs," Primary Care, Vol. 9, No. 4, pp. 743-756 (December 1982).	A 000350-000365				
176	U.S. Patent No. 2,822,314.	A 0006050-0006051				
177	U.S. Patent No. 4,749,700.	AS-MEDA 002181-002195				
178	E. Keeney, "Histamine and the Antihistaminic Drugs," California Medicine, Vol. 72, No. 1, pp. 377-389 (May 1950).	A 000089-000104				

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PTX	Description	Bates Range	PDX	Admission		Date Admitted
				No Obj.	Objection Basis	
179	Scudi, JV. "Study of Drug Action on Mammalian Ciliated Epithelium." J. of Pharmacology and Experimental Therapeutics. Vol. 101, 1951: 132-37.					
180	S.M. Feinberg, "Drugs In Allergy," Trans. Amer. Acad. of O&O, Vol. 124 (April 1950), pp. 283-286.	A 000085-000088				
181	Guerrant, JL. "Palpebral Dermatitis." Am. J. Ophthalmol. Vol. 34, 1951: 1318-20.					
182	Orange Book entry for Levocabastine Hydrochloride. <a href="http://www.accessdata.fda.gov">http://www.accessdata.fda.gov</a> . Accessed on 9/9/2007.					
183	U.S. Patent No. 3,144,485.	A 006031-006034				
184	U.S. Patent No. 4,313,931.	A 000329-000339				
185	U.S. Patent No. 4,628,055.	A 006052-006059				
186	U.S. Patent No. 3,878,217.	A 000147-000156				
187	U.S. Patent No. 4,254,129.	A 000294-000304				
188	U.S. Patent No. 4,430,343.	A 000401-000413				
189	U.S. Patent No. 4,728,509.	A 006024-006030				
190	U.S. Patent No. 4,795,754.	A 006035-006041				
191	Astelin Net Sales Figures	AS 006777-006779				
192	Bowser, CS. "New Antihistamine Nasal Spray Safe, with Less Incidence of Bad/Bitter Taste Versus Azelastine." Presented at ACAAI. November 13, 2006.	A 006137-006138				
193	Uniform Jury Instructions for Patent Cases in the United States District Court for the District of Delaware. pp. 40, 43, 55.					
194	Curriculum Vitae of Dr. Richard N. Dalby					
195	Excerpts of ANDA 77-954	A 000942, A 000956, A 000959, A 000965-000967, A 001034, A 001053, A 001400, A 001402				
196	Current Concepts in the Pharmaceutical Sciences: Dosage Form Design and Bioavailability. Ed. Swarbrick. Philadelphia: Lea & Febiger, 1973. 110.					
197	Harris, AS. "Effect of Viscosity on Particle Size Deposition." Journal of Pharmaceutical Sciences. Vol. 77, No. 5, 1988: 405-08.					

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PTX	Description	Bates Range	PDX	Admission		Date Admitted
				No Obj.	Objection Basis	
198	Physicians' Desk Reference, 41st Edition. Ed. Huff. Oradell: Medical Economics Company, Inc., 1987. 2005.					
199	The United States Pharmacopeia, 16th Edition. Rockville: United States Pharmacopeial Convention, 1985. 1329.					
200	Chart Illustrating Infringement - Dalby Report Exhibit					
201	List of Previous Expert Testimony					
202	List of Documents Reviewed by Richard N. Dalby					
203	Remington's Pharmaceutical Sciences, 17th Edition. Ed. Gennaro. Easton: Mack Publishing Company, 1985. 63, 82, 441, 1417, 1492-1517.					
204	Webster's Seventh New Collegiate Dictionary. Springfield: G. & C. Merriam & Company, 1967. 31.					
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208	Allergy Principles and Practice, 2d Edition. Ed. Middleton, Reed, Ellis. St. Louis: C.V. Mosby Company, 1983. 1101-03, 1112-15.					
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210	Goodman and Gilman's The Pharmacological Basis of Therapeutics, 7th Edition. New York: MacMillan Publishing Company, 1985. 9.					
211	Allergic Diseases, 2d Edition. Ed. Patterson. Philadelphia: J.P. Lippincott Company, 1980. 179, 197-98.					
212	Chart Illustrating Infringement - Meltzer Report Exhibit					
213	List of Documents Reviewed by Eli O. Meltzer					
214	Schaffe and Seidmon, "The Intranasal Use of Propenpyridamine Maleate and Chlorphenpyridamine Maleate in Allergic Rhinitis," Annals of Allergy, Vol. 10, 1952: 194-96.	A 008141-008146				
215	RxMed: Pharmaceutical Information - Metretion					

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PTX	Description	Bates Range	PDX	Admission		Date Admitted
				No Obj.	Objection Basis	
216	A. Togias, R.M. Naclerio, J. Warner, D. Proud, A. Kagey-Sobotka, I. Nimmagadda, P.S. Norman and L. Lichenstein, "Demonstration of Inhibition of Mediator Release From Human Mast Cells by Azatadine Base," Journal of the American Medical Association, Vol. 255, No. 2, pp. 225-229) (Jan. 10, 1986).	A 000455-000461				
217	R.M. Naclerio, H.L. Meier, A. Kagey-Sobotka, P.S. Norman and L.M. Lichenstein, "In Vivo Model for the Evaluation of Topical Antiallergic Medications," Archives of Otolaryngology, Vol. 110, No. 1, pp. 25-27 (January 1984).	A 000396-000400				
218	Remington's Pharmaceutical Sciences, 14th Edition. Ed. Osol. Easton: Mack Publishing Company. 1970. 1143, 1152.					
219	Physicians' Desk Reference for Nonprescription Drugs, First Edition, pp. 502-03, 506, 522, 539, 553, 616, 637-38, 646, 654-55 (1980).	A 000276-000289				
220	U. Pipkorn, M. Bende, J. Hedner, T. Hedner, "A Double-Blind Evaluation of Topical Levocabastine, a New Specific HI Antagonist in Patients with Allergic Conjunctivitis," Allergy, Vol. 40, pp. 491-496 (1995).	A 000427-000434				
221	G. Vanden Bussche, "Levocabastine Hydrochloride." Vol. 11, Drugs of the Future. No. 10, pp. 841-843 (1986).	A 000469-000471				
222	M. Bende, U. Pipkorn, "Topical levocabastine, a selective HI antagonist, in seasonal allergic rhinoconjunctivitis," Allergy 1987, 42, pp. 512-515.	A 000558-000563				
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PTX	Description	Bates Range	PDX	Admission		Date Admitted
				No Obj.	Objection Basis	
226	Meltzer, EO. "Azelastine nasal spray in the management of seasonal allergic rhinitis." Annals of Allergy. Volume 72, 1994: 354-359.					
227	Gaspar, H. "Comparative efficacy of azelastine nasal spray and terfenadine in seasonal and perennial rhinitis." Allergy. Volume 49, 1994: 152-158.					
228	Weiner, J. "Intranasal corticosteroids versus oral H1 receptor antagonists in allergic rhinitis: systematic review of randomised controlled trials." BMJ. Volume 317, 1998: 1624-1629.					
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230	Berger, W. "Efficacy of azelastine nasal spray in patients with an unsatisfactory response to loratadine." Annals of Allergy, Asthma & Immunology. Volume 91, 2003: 205-211.	ASC 000021-000027				
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236	Intentionally left blank					
237	Intentionally left blank					
238	Apotex's Paragraph IV Certification dated January 24, 2006.	A 000050-000078				



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PTX	Description	Bates Range	PDX	Admission		Date Admitted
				No Obj.	Objection Basis	
239	W. Diamantis, J.E. Harrison, J. Melton, J.L. Perhach, Jr., R.D. Sofia, "In Vivo and In Vitro HI Antagonist Properties of Azelastine," Vol. 23, No. 3, The Pharmacologist (1981), p. 149.	A 000290-000293				
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243	Y.M. Chien, Transnasal Systemic Medications Fundamentals, Developmental Concepts and Biomedical Assessments, Title page, pp. 80-81 and 98 (1985).	AS-MEDA 010157-010160				
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PTX	Description	Bates Range	PDX	Admission		Date Admitted
				No Obj.	Objection Basis	
251	K. Tatsumi, T. Ou, H. Yamada and H. Yoshimura, "Studies on Metabolic Fate of a New Antiallergic Agent, Azelastine (4-(p-Chlorobenzyl)-2--Methylperhydroazepinyl-(4)]-1-(2H)-Phthalazinone Hydrochloride)," Japan J. Pharmacol. Vol. 30, pp. 37-48 (1980).	A 000242-000253				
252	M. Okuda, et al., Oto-Rhino-Laryngology Tokyo, Vol 23, Suppl. 6, pp. 441-461(1980).	A 000254-000275				
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253	S.W. Lam, R.C. Meyer and L.T. Takahashi, "Determination of Thimerosal in Ophthalmic Solutions by Redial Compression Separation HPLC." Journal of Parenteral Science and Technology, Vol. 35, No. 5, pp.262-265 (September-October 1981).	A 000305-000308				
254	W. Diamantis, N. Chand, J.E. Harrison, J. Pillar, J.L. Perhach, Jr. and R.D. Sofia, "Inhibition of Release of SRS-A and Its Antagonism by Azelastine (A). An HI Antagonist-Antiallergic Agent," The Pharmacologist. 24, p.200 (1982).	A 000325-000328				
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257	K. Tatsumi, H. Yamada, H. Yoshimura, Y. Nishizawa, M. Sakai, H. Mizuo and C. Yamato, "Metabolism of an Antiallergic Agent, Azelastine (4-(p-Chlorobenzyl)-2-[N-Methylperhydroazepinyl-(4)]-1-(2H)-Phthalinone Hydrochloride) in Rats and Guinea Pigs," Hiroshima Journal of Medical Sciences, Vol. 33, No. 4, pp. 669-678 (December 1984)	A 000416-000426				

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PTX	Description	Bates Range	PDX	Admission		Date Admitted
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258	N. Chand, J. Pillar, W. Diamantis and R.D. Sofia. "Inhibition of Allergic Histamine Release by Azelastine and Selected Antiallergic Drugs from Rabbit Leukocytes," International Archives of Allergy and Applied Immunology, Vol. 77, No. 4, pp. 451-455 (1985)	A 000435-000441				
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261	H.A. Orgel, E. Meltzer, J. Kemp and M.J. Welch, "Clinical, rhinomanometric, and cytologic evaluation of seasonal allergic rhinitis treated with beclomethasone dipropionate as aqueous nasal spray or pressurized aerosol," J. Allergy Clin. Immunol., Vol. 77, No. 6, pp. 858-864 (June 1986).	A 000462-000468				
262	T.E. Havas, P. Cole, L. Parker, D. Oprysk and A. Ayiomamitis, "The effects of combined H1 and H2 histamine antagonists on alterations in nasal airflow resistance induced by topical histamine provocation," J. allergy Clin. Immunol., vol. 78, No. 5, Part 1, pp. 856-860 (November 1986).	A 000472-000476				
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PTX	Description	Bates Range	PDX	Admission		Date Admitted
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267	J. Dolovich, L. Kennedy, F. Vickerson and F. Kazim, "Control of the hypersecretion of vasomotor rhinitis by topical ipratropium bromide," The Journal of Allergy and Clinical Immunology, Vol. 80, No. 3, Part 1, pp. 274-278 (September 1987).	A 000541-000547				
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270	Y. W. Chien and S. Chang, "Intranasal Drug Delivery For Systemic Medications," CRC Critical Reviews in Therapeutic Drug Carrier Systems, Vol. 4, Issue 2, pp. 67-194 (1987).	A 000581-000712				
271	E.R. Weeke, "Epidemiology of Hay Fever and Perennial Allergic Rhinitis," Monogr. Allergy, Vol. 21, pp. 1-20 (1987).	A 000713-000734				
272	M.H. Shin, F. Baroody, d. Proud, A. Kagley-Sohotka, L.M. Lichtenstein and R.M. Naclerio, "The effect of azelastine on the early allergic response," Clinical and Experimental Allergy, Vol. 22, pp. 289-295 (1992).	A 000754-000762				
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PTX	Description	Bates Range	PDX	Admission		Date Admitted
				No Obj.	Objection Basis	
275	W.E. Berger, S.M. Fineman, P. Lieberman, R.M. Miles and the Rhinitis Study Groups, "Double-blind trials of azelastine nasal spray monotherapy versus combination therapy with loratadine tablets and beclomethasone nasal spray inpatients with seasonal allergic rhinitis," <i>Annals of Allergy, Asthma, &amp; Immunology</i> , Vol. 82, pp. 535-541 (June 1999).	A 000785-000791				
276	S.J. Golden and T.J. Craig, "Efficacy and safety of azelastine nasal spray for the treatment of allergic rhinitis," <i>JAOA</i> , Vol. 99, No. 7, Suppl. To July 1999, pp. S7-S11 (1999).	A 000792-000797				
277	PCT Application WO 01/52818.	A 000798-000819				
278	C. Duate, M. Baehre, S. Gharakhanian, F. Leynadier and the French Azelastine Study Group, "Treatment of Severe Seasonal Rhinoconjunctivitis by a Combination of Azelastine Nasal Spray and Eye Drops: A Double-Blind, Double-Placebo Study," <i>J. Invest. Allergol Clin Immunol</i> , Vol. 11(1), pp. 34-40 (2001).	A 000828-000834				
279	Physicians' Desk Reference, 59th Edition, Astelin and Optivar product monographs, pp. 1973-1976 (2005).	A 000835-000840				
280	Asta-Werke June 30, 1983 report regarding "Solubility of Azelastine and Azelastine salts."	AS 002172-002181				
280A	English Translation of Asta-Werke June 30, 1983 report regarding "Solubility of Azelastine and Azelastine salts."	AZ 008114-8124				
281	J. Knothe and E. Aschoff, "Experimental Examinations of the Effect of some Mucosa Decongesting Nasal Drops," <i>Ear-Nose-Throat Diseases</i> , pp. 2384 - 2388 (1969)	A 006114-006118				
281A	English Translation of J. Knothe and E. Aschoff, "Experimental Examinations of the Effect of some Mucosa Decongesting Nasal Drops," <i>Ear-Nose-Throat Diseases</i> , pp. 2384 - 2388 (1969)					
282	Excerpts from "Aerosols in Medicine Principles, Diagnoses and Therapy," (Elsevier Science Publishers B.V. 1985) (Book cover, Title page; Copyright page; pp. xi-xvii; Chapter 1 (pp. 1-20); Chapter 3 (pp. 53-76); Chapter 5 (pp. 123-147); pp. 198-199; pp. 207-209; Chapter 10 (pp. 261-262; 268-272; 283-284); Chapter 11 (pp. 285; 290-293; 307-308).	A 006220-006319				

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PTX	Description	Bates Range	PDX	Admission		Date Admitted
				No Obj.	Objection Basis	
283	Excerpts from "Remington's Pharmaceutical Sciences," Fourteenth Ed. (1970) (Title page; Copyright page; Table of Contents (p. xi); Chapter 64 (pp. 1142-1 153); Chapter 80 (pp. 1478-1500); Chapter 83 (pp. 1545-1577); Chapter 85 (pp. 1594-1595; 1597-1625); Chapter 90 (pp. 1729-1753).	A 006444-006570				
284	Website information from Adcock Ingram regarding Antusun-Privin.	A 006011-006015				
285	U.S. Patent No. 4,738,984.	A 006042-006049				
286	Expert's Report.	MPAT 000484-000489				
286A	English Translation of Expert's Report.					
287	H. Breuninger, "Nasentropfen, Ohrentropfen." HNO, pp. 65-68 (March 1971).	A 006107-006110				
287A	English Translation of H. Breuninger, "Nasentropfen, Ohrentropfen." HNO, pp. 65-68 (March 1971).					
288	P.E. Grumbach, I. Kapetanidis, A. Mirmanoff, A. Paley and M. Savary, "Erfahrungen mit Präparaten," Schweizerische Medizinische Wochenschrift Nr. 11, Bd. 96, pp. 358-360 (1966).	A 006111-006113				
288A	English Translation of P.E. Grumbach, I. Kapetanidis, A. Mirmanoff, A. Paley and M. Savary, "Erfahrungen mit Präparaten," Schweizerische Medizinische Wochenschrift Nr. 11, Bd. 96, pp. 358-360 (1966).					
289	"Allergische Rhinitis - Eine Crux Medicorum - Neue Wege in der Therapie," Z. Allg. Med. 57, pp. 1939-1940 (1981)	A 006323-006324				
289A	English Translation of "Allergische Rhinitis - Eine Crux Medicorum - Neue Wege in der Therapie," Z. Allg. Med. 57, pp. 1939-1940 (1981)					
290	P.H. Sauer, "Rhomanometrische Kontrollen des Nasenwiderstandes - Nach Einmaliger Applikation von Vobrocil-Dosierspray," medwelt Bd. 34, pp. 63/1319-72/1321.	A 006320-006322				
290A	English Translation of P.H. Sauer, "Rhomanometrische Kontrollen des Nasenwiderstandes - Nach Einmaliger Applikation von Vobrocil-Dosierspray," medwelt Bd. 34, pp. 63/1319-72/1321.					
291	Subpoena for Naresh Chand	CH 000197-000208				
292	Pubmed search for 'chand n'	CH 000053-000065				

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PTX	Description	Bates Range	PDX	Admission		Date Admitted
				No Obj.	Objection Basis	
293	Chand, "Is airway hyperactivity in asthma due to histamine H2 receptor deficiency?" Medical Hypotheses 6: 1105-1112 (1980)	CH 000066-000073				
294	Chand, "Inhibition of allergic and non-allergic histamine secretion from rat peritoneal mast cells by calcium antagonists," Br. J. Pharmac. 83 (1984) 899-902.	CH 000085-000088				
295	Wallace Laboratories Report No. DR-90-92, "Formula Rationale for Azelastine Hydrochloride Nasal Solution, 0.1 % w/v," January 31, 1991.	ASN 000935-000954				
296	U.S. Patent No. 4,602,099					
297	Plaintiffs Objections and Supplemental Response to Apotex's Interrogatory No. 14.					
298	C.D. Logemann, L.M. Rankin, "Newer Intranasal Migraine Medications," American Family Physician (2000)					
299	Migraine Agents, Medco Health Solutions					
300	Reproduction of Example 24 from German Patent No. 21 64 058 by the Langer Laboratory at MIT					
301	Expert's opinion regarding the use of azelastine or its physiologically compatible salts for nasal and ocular application	MPAT 000277-000279				
302	Decision about the revocation of the European Patent, from the Munich European Patent Office	MPAT 000404-000420				
303	Asta Pharma Report dated September 13 1988	AS-MEDA 003522-003525				
304	USPTO Online Patent Query for 5,164,194					
305	R. Lancaster, "Topical of Systemic Therapy?" pp. 47-53 (1983).	AS-MEDA 001860-001863				
306	N. Chand, K. Nolan, W. Diamantis and R.D. Sofia, "Effect of Aerosolized Azelastine on Acute Lung Anaphylaxis in Guinea Pigs (GP) Sensitized by Two Different Procedures," The Pharmacologist, Vol. 27, No. 1 (1985) (Abstract 76) (Defendants' Deposition Exhibit No. 26).					
307	N. Chand, J. Pillar, W. Diamantis and R.D. Sofia, "Inhibition of IgE-mediated allergic histamine release from rat peritoneal mast cells by azelastine and selected antiallergic drugs," Agents and Actions, Vol. 6, pp. 3 18-322 (1985).	A 006062-006066				

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PTX	Description	Bates Range	PDX	Admission		Date Admitted
				No Obj.	Objection Basis	
308	J. Weiler and E. Meltzer, "Azelastine nasal spray as adjunctive therapy to azelastine tablets in the management of seasonal allergic rhinitis," <i>Annals of Allergy, Asthma, &amp; Immunology</i> , Vol. 79, pp. 327-332 (October 1997).					
309	A. Toggias, D. Proud, A. Kagey-Sobotka, P. Norman, L. Lichtenstein and R. Naclerio, "The effect of a topical tricyclic antihistamine on the response of the nasal mucosa to challenge with cold, dry air and histamine," <i>J. Allergy Clin. Immunol.</i> , Vol. 79, No. 4, April 1987, pp. 599-604.	A 000925-000930				
310	Excerpts from The United States Pharmacopoeia - Twenty-First Revision (Official from January 1, 1985), Title page, Copyright page, pp. 1329.1333-1343.1635.1639.1655 and 1657- 1660.	AS-MEDA 002113-002133				
311	Excerpts from Remington's Pharmaceutical Sciences, Fourteenth Edition, 1970, Title page, Title Page for Part VIII, pp. 1461-1462, 1492. 1594-1598. 1610 and 1616.	AS-MEDA 002134-002145				
312	Excerpts from Y.W. Chien, "Transnasal Systemic Medications Fundamentals, Development Concepts and Biomedical Assessments," (1 985). Title page, pp. 80-81 and 98.	AS-MEDA 002328-002331				
313	N. Chand, "Effect of Azelastine, Its d- and l-Isomers, Putative Metabolites and Analogs on IgE-Mediated Passive Cutaneous Anaphylaxis in Rats." Wallace Laboratories. PH-86-32.	AZ 002575-002585				
314	N. Chand, "Effect of Newer Analogs of Azelastine on Allergic Histamine Secretion from Rat Peritoneal Mast Cells," Wallace Laboratories. PH-89-2.	AZ 002969-002984				
315	N. Chand, "Azelastine Hydrochloride: Influence of Isomers, Metabolites and Analogs of Azelastine and Selected Antiallergic Drugs on Antigen-Induced Contractile Responses and Subsequent Development of Airway Hyperreactivity to Cold in Isolated Rat Trachea." Wallace Laboratories. PH-86-14.	AZ 002388-002422				
316	N. Chand, "Effect of Azelastine, Its Putative Metabolites, Isomers and Analogs on Calcium Ionophore A23187-Stimulated Leukotriene B4 Synthesis in Rat Peritoneal Cells (Radioimmunoassay)," Wallace Laboratories. PH-86-35.	AZ 002614-002635				



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PTX	Description	Bates Range	PDX	Admission		Date Admitted
				No Obj.	Objection Basis	
317	N. Chand, "Influence of Azelastine, Its Metabolites and Analogs on Aeroallergen-Induced Pulmonary Mechanics Changes in Guinea Pig Asthma Model," Wallace Laboratories, PH-85-10.	AZ 002216-002223				
318	N. Chand, "Antagonism of Histamine by Azelastine, Its Isomers, Putative Metabolites and Analogs in Isolated Guinea Pig Ileum," Wallace Laboratories, PH-86-16.	AZ 002423-002440				
319	J.M. Weiler, A. Donnelly, B.H. Campbell, J.T. Connell, L. Diamond, L.H. Hamilton, R.R. Rosenthal, G.R. Hemsworth and J.L. Perhach, Jr., "Multicenter, double-blind, multiple-dose, parallel-groups efficacy and safety trial of azelastine, chlorpheniramine, and placebo in the treatment of spring allergic rhinitis," J. Allergy Clin. Immunol., Vol. 82, No. 5, Part 1, pp. 801-811 (November 1988).	A 000931-000941				
320	T. Fukutake, "Studies of clinical effect of E - 0659 on the so - called vasomotor rhinitis," Study No. 120, Degussa GB Pharma Report, (1983).	ASN 074954-074964				
321	D.K. Ledford, "Chapter 9, Rhinitis" and P. Lieberman, "Chapter 17, Antihistamines," Allergic Diseases - Diagnosis and Treatment, Cover page, Copyright page, pp. 159-182 (2nd Ed. 2000).					
322	Allergy Principles & Practice, "Allergic and Nonallergic Rhinitis," pp. 1005, 1014 & "Chapter 45 -Antihistamines," (5th Ed. 1998).					
323	Asthma and Rhinitis, "Chapter 100," p. 1330 (1995).					
324	Hill et al., (1978) Med J. Austr. 2:603-4.					
325	Gale et al., (1980) Clin. Allergy 10:527-33.					
326	Fokkens et al. (2007) Allergy 62:1078-84.					
327	Bielory et al., (2007) Medscape General Medicine 9:35.					
328	Andersen, et al., (1987) Allergy 42:343-51.					
329	German Offenlegungsschrift DE 35 30793					
329A	English Translation of German Offenlegungsschrift DE 35 30793					
330	P 34 33 776.8					
330A	English Translation of P 34 33 776.8					

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PTX	Description	Bates Range	PDX	Admission		Date Admitted
				No Obj.	Objection Basis	
331	Memorandum entitled Memo for Dr Aurich dated September 30 1985	AS-MEDA 009924				
331A	English Translation of Memorandum entitled Memo for Dr Aurich dated September 30 1985					
332	German Offenlegungsschrift 21 64 058					
332A	English Translation of German Offenlegungsschrift 21 64 058					
333	Declaration Under Rule 132 of Dr Achterath-Tuckermann dated February 16 1987					
334	Declaration of Dr Szelenyi dated January 23 1990	MP 000063-64				
335	European Patent No 316 633					
335A	English Translation of European Patent No 316 633					
336	Decision of the Opposition Division of the European Patent Office mailed March 28 1996					
336A	English Translation of Decision of the Opposition Division of the European Patent Office mailed March 28 1996					
337	Decision of the Technical Court of Appeals 3.3.2 dated April 2000					
337A	English Translation of Decision of the Technical Court of Appeals 3.3.2 dated April 2000					
338	U.S. Patent No 3813384					
339	December 1982 Asta-Werke AG Toxicology Report	ATI 001098-001266				
340	Abstract 76 Chand Nolan Diamantis Sofia R.D 1985 Pharmacologist 27162					
341	Single page document with Beispiel 24	AS-MEDA 001568				
341A	English Translation of Single page document with Beispiel 24					
342	Internal Letter dated September 1985 from Dr Aurich to Prof Dr Breuel	AS-MEDA 000601-000602				
342A	English Translation of Internal Letter dated September 1985 from Dr Aurich to Prof Dr Breuel					
343	Internal Memo prepared by Dr Hettche to Dr Herbst dated August 13 1990	AS-MEDA 001345				
343A	English Translation of Internal Memo prepared by Dr Hettche to Dr Herbst dated August 13 1990					
344	Handwritten note by Dr Hettche dated February 18 1986	AS-MEDA 001938				

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PTX	Description	Bates Range	PDX	Admission		Date Admitted
				No Obj.	Objection Basis	
344A	English Translation of Handwritten note by Dr Hettche dated February 18 1986					
345	Handwritten note by Dr Hettche to Dr Ulbrich dated August 12 1987	AS-MEDA 000600				
345A	English Translation of Handwritten note by Dr Hettche to Dr Ulbrich dated August 12 1987					
346	German Patent Application No 3539873.6					
346A	English Translation of German Patent Application No 3539873.6					
347	Antistun-Privin package insert					
348	Single page 725 taken from reference involving Medications for the eye ear and nose	AS-MEDA 007755				
348A	English Translation of Single page 725 taken from reference involving Medications for the eye ear and nose					
349	Aberer Tappeiner 1988 Wiener klinische Wochenschrzfi 1988 Dec 2: 100(23):763-765.					
349A	English Translation of Aberer Tappeiner 1988 Wiener klinische Wochenschrzfi 1988 Dec 2: 100(23):763-765.					
350	Document entitled Inhibition of allergic histamine release from rat peritoneal mast cells attached as part of Dr Szelenyis January 23 1990 Declaration					
351	Declaration of Dr Istvan Szelenyi dated June 1, 1990					
352	1988-02-22 Asta "Expert Report on Chemical and Pharmaceutical Documentation according to § 24 (1) AMG 1976 Azelastine Intranasal Spray"	AS 003212-003236				
353	Assignment Agreement	AS 007016-007027				
354	Schedule E - Assignment and Assumption Agreement	AS 007028-007033				
355	Exhibit B - License Agreement	AS 007034-007036				
356	Exhibit C - Amendment to Azelastine License Agreement	AS 007037-007038				
357	1996-07-31 Letter from Black to Engel re 1982-08-16 License Agreement	AS 007039-007040				
358	2001-04-11 Letter from Stewart to Levine re 1982-08-16 License Agreement	AS 007041-007042				
359	2001-04-11 Letter from Levine and Stewart to Peterseim re 1982-08-16 License Agreement	AS 007043-007044				



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360	2002-05-17 Interest Purchase Agreement	AS 007045-007067				
361	Exhibit A - Agreement	AS 007068-007079				
362	Schedule III - Patent Assignment	AS 007080-007085				
363	Schedule IV - Letter dated July 31, 1996 (To be attached)	AS 007086-007088				
364	1987-02-27 Wallace draft minutes of the February 10-11, 1987 azelastine satellite meeting	AS 007208-007235				
365	1982-08-16 License Agreement between Carter-Wallace and Chemiewerk Homburg	AS 007908-007950				
366	Alcon Press Release re Opatanol	ASC 000001				
367	"Questions and Answers on the Withdrawal of an Application for an Extension of the Marketing Authorisation for Opatanol"	ASC 000002-000003				
368	Lieberman, Efficacy of azelastine nasal spray in the treatment of vasomotor (perennial nonallergic) rhinitis (2001)	ASC 000004-000011				
369	Berger, Double-blind trials of azelastine nasal spray monotherapy versus combination therapy with loratadine tablets and beclomethasone nasal spray in patients with seasonal allergic rhinitis (1999)	ASC 000012-000018				
370	Berger, Efficacy of azelastine nasal spray in patients with an unsatisfactory response to loratadine (2003)	ASC 000019-000027				
371	Charpin, A multicenter clinical study of the efficacy and tolerability of azelastine nasal spray in the treatment of seasonal allergic rhinitis: a comparison with oral cetirizine (1995)	ASC 000028-000033				
372	Ciprandi, Treatment of nonallergic perennial rhinitis (2004)	ASC 000034-000042				
373	Conde Hernandez, DJ. "Comparison of Azelastine Nasal Spray and Oral Ebastine in Treating Seasonal Allergic Rhinitis." Curr. Med. Res. Opin.. Volume 13, 1995: 299-304.	ASC 000043-000048				
374	Corre, Effectiveness of Azelastine Nasal Spray Compared with Oral Cetirizine in Patients with Seasonal Allergic Rhinitis (2005)	ASC 000049-000061				
375	Davies, Antihistamines: topical vs oral administration (1996)	ASC 000062-000070				
376	Dorow, Efficacy and tolerability of Azelastine Nasal Spray in Patients with Allergic Rhinitis Compared to Placebo and Budenoside (1993)	ASC 000071-000074				

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				No Obj.	Objection Basis	
377	Falsera, Comparative Efficacy and Safety of Azelastine and Levocabastine Nasal Sprays in Patients with Seasonal Allergic Rhinitis (2001)	ASC 000075-000081				
378	2006-02-14 Letter from Matthews to Brasseur re Opatanol	ASC 000082				
379	Gambardella, A Comparison of the Efficacy of Azelastine Nasal Spray and Loratadine Tablets in the Treatment of Seasonal Allergic Rhinitis (1993)	ASC 000083-000092				
380	Gaspar, Investigation of Long-term Efficacy and Tolerability of Azelastine Nasal Spray in the Treatment of Perennial Allergic Rhinitis (1993)	ASC 000100-000106				
381	Gaspar, Intranasal Treatment of Perennial Allergic Rhinitis: Comparison of azelastine nasal spray and budesonide nasal aerosol (1993)	ASC 000107-000111				
382	Herman, A randomized double-blind placebo controlled study of azelastine nasal spray in children with perennial rhinitis (1997)	ASC 000112-000120				
383	Horak, Azelastine nasal spray and desloratadine tablets in pollen-induced seasonal allergic rhinitis: a PD study of onset of action and efficacy (2006)	ASC 000121-000129				
384	LaForce, Efficacy of azelastine nasal spray in seasonal allergic rhinitis patients who remain symptomatic after treatment with fexofenadine (2004)	ASC 000130-000135				
385	Lieberman, Management of allergic rhinitis with a combination anti-histamine/anti-inflammatory agent (1999)	ASC 000136-000141				
386	Meltzer, Efficacy of azelastine in perennial allergic rhinitis: Clinical and rhinomanometric evaluation (1987)	ASC 000142-000150				
387	Passali, A Comparison of Azelastine Nasal Spray and Cetirizine Tablets in the Treatment of Allergic Rhinitis (1994)	ASC 000151-000159				
388	Ratner et al., (1994) J. Allergy Clin. Immunol. 94:818-25	ASC 000160-000168				
389	W.W. Storms, D.S. Pearlman, P. Chervinsky, J. Grossman, P.C. Halverson, J.J. Freitag and M.D. Widlitz, "Effectiveness of Azelastine Nasal Solution in Seasonal Allergic Rhinitis," ENT, Vol. 73, No. 6 (June 1994), pp. 382-394 (including Front Cover and Copyright page).	ASC 000169-000179				

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				No Obj.	Objection Basis	
390	van de Henning, A gap in surface therapy: topical antihistamines (1991)	ASC 000196-000202				
391	Wang, Effect of Topical Applications of budenoside and Azelastine on Nasal Symptoms, Eosinophil Count and Mediator Release in Atopic Patients after Nasal Allergen Challenge during the Pollen Season (1997)	ASC 000203-000212				
392	Wober, Evaluation of the Drug Monitoring Programme of Azelastine Hydrochloride Nasal Spray in the Treatment of Allergic Rhinitis in Children under 13 Years of Age (1997)	ASC 000213-000217				
393	Wober, Efficacy and tolerability of azelastine nasal spray in the treatment of allergic rhinitis: large scale experience in community practice (1997)	ASC 000218-000228				
394	Gaspar, Azelastine nasal spray relieves symptoms of allergic rhinitis (1990)	ASN 038857-038858				
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396	Asta Clinical Study No. A 5610-2610, Comparison of the Efficacy and Tolerability of an Azelastine HCl Nasal Spray with those of Terfenadine on Six-Week Treatment of Patients with Allergic Rhinitis (Seasonal)	ASN 038878-038881				
397	Asta Clinical Study No. A 5610-2606, Comparison of the Efficacy and Tolerability of an Azelastine HCl Nasal Spray with those of Terfenadine on Six-Week Treatment of Patients with Allergic Rhinitis (Seasonal)	ASN 052451-052453				
398	Asta Clinical Study No. A 5610-2613, Comparison of the Efficacy and Tolerability of an Azelastine HCl Nasal Spray with those of Terfenadine on Six-Week Treatment of Patients with Allergic Rhinitis (Seasonal)	ASN 054262-054264				
399	Summary of Efficacy Studies re: Azelastine	ASN 075390-075417				
400	1984-12-20 Memo re: Meeting with Chemiewerk Homburg and Organon: December, 1984	AZ 000102-000109				
401	1986-09-04 Wallace Labs Report No. TC-865-15 re: Summary of Toxicology Studies	AZ 005761-005803				

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				No Obj.	Objection Basis	
402	1984-08-09 Asta Report on the Testing of the Primary Cutaneous Irritation (Local Irritancy) of two Formulations of Azelastine Hydrochloride (Cream, Gel) after repeated Application to the Skin of the Rabbit (Patch-Test)	AZ 006124-006159				
403	Apotex's Response to Plaintiff's First Request for the Production of Documents and Things					
404	Apotex, Inc. and Apotex Corp.'s Responses to Plaintiff's First Set of Interrogatories					
405	Apotex's First Supplemental Response to Plaintiff's First Set of Interrogatories					
406	Apotex's First Supplemental Response to Plaintiff's First Set of Requests for Admission					
407	Ansel, "Introduction to Pharmaceutical Dosage Forms" (pp. 333-349)	A 000194-000212				
408	Azelastine Hydrochloride Nasal Spray 137mcg: Listed Drug Labeling - Bottle Label	A 000981-000983				
409	Azelastine Hydrochloride Nasal Spray 137mcg: Listed Drug Labeling - Carton	A 000984-000988				
410	Cheng, D. Y., "Cascade Impactor Method for the Droplet Size Characterization of a Metered-Dose Nasal Spray," J. Pharma. Sci., Vol. 73, No. 3, March 1984, pp. 344-348.	A 005981-005985				
411	Taschenbuch der parktischen Medizin	AS-MEDA 000366-000368				
411A	English Translation of Taschenbuch der parktischen Medizin					
412	Pharmazeutische Technologie	AS-MEDA 000615-000618				
412A	English Translation of Pharmazeutische Technologie					
413	Externe Therapie von Hautkrankheiten	AS-MEDA 000639-000646				
413A	English Translation of Externe Therapie von Hautkrankheiten					
414	Asta Pharma Report re "Azelastine HCl 0.1%: Effects on ciliary activity of guinea pig nasal mucosa after local administration" (1992)	AS-MEDA 001224-001225				

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				No Obj.	Objection Basis	
415	Centre de Recherches Biologiques Report re "Azelastrine HCl 0.1%: Effects on ciliary activity of guinea pig nasal mucosa after local administration"	AS-MEDA 001226-001249				
416	Funktionelle Dermatologie	AS-MEDA 009081-009082				
416A	English Translation of Funktionelle Dermatologie					
417	6.9.1985 Degussa Memo from Aurich to Hetteche re Azelastrin-Nasenspray	AS-MEDA 009738				
417A	English Translation of 6.9.1985 Degussa Memo from Aurich to Hetteche re Azelastrin-Nasenspray					
418	Chand et al., "Inhibition of Leukotriene (SRS-A)-mediated allergic bronchospasm by Azelastrine, a Novel <i>Orally Effective</i> Antiasthmatic Drug," 241 The Journal of Allergy and Clinical Immunology (1983)					
419	Chand et al., "Inhibition of IgE-mediated passive cutaneous anaphylaxis (PCA) by azelastrine in rat," The Journal of Allergy and Clinical Immunology (1984)					
420	Chand et al., "Dissociation of Antiallergic (Anti-PCA) Activity From the Antihistaminic and Antiserotonin Activities of Azelastrine," 138 The Pharmacologist (1984).					
421	Chand et al., "Inhibition of Allergic Histamine Secretion From RPMC by Azelastrine, a Novel, <i>Orally Acting</i> Antiallergic Agent, 419 The Pharmacologist (1983).					
422	Chand et al., "Inhibition of IgE-mediated Allergic Histamine Release by Azelastrine from Rabbit Basophils," Federal Proceedings (1984)					
423	Chand et al., "Antagonism of Leukotrienes, Calcium and Histamine by Azelastrine," The Pharmacologist (1984)					
424	Chand et al., "Pharmacological Modulation of In Vitro Anaphylactic Responses of Isolated Guinea Pig Tracheal Rings by Azelastrine and Inhibitors of Arachidonic Acid (AA) Metabolism," Federation Proceedings (1984)					
425	Chand et al., "Antagonism of histamine and leukotrienes by azelastrine in isolated guinea pig ileum," Agents and Actions, vol. 19 (1986)					



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PTX	Description	Bates Range	PDX	Admission No Obj.	Objection Basis	Date Admitted
426	Chand et al., "Inhibition of Antigen-induced Airway Hyperreactivity (AIAH) to Cold Provocation by Azelastine and Selected Antihistaminic Drugs in Rat Isolated Tracheal Segments," 130 Journal of Allergy and Clinical Immunology (1/1987)					
427	Chand et al., "Effect of Azelastine and Diltiazem on Activation (First) and Release (Second) Stages of Allergic Histamine Secretion in Rabbit Leukocytes," Federation Proceedings (3/1987)					
428	Chand et al., "Inhibition of 5-HETE, LTB4 and LTC4 Synthesis by Azelastine and its d- and l- Isomers in Rat Mixed Peritoneal Cells," American Review of Respiratory Disease (4/1987)					
429	Chand et al., "Inhibition of <i>Acute Bronchial Anaphylaxis</i> by Azelastine (AZ) in Aerosolized-Sensitized Guinea Pig (GP)," 671 Annals of Allergy (1985)					
430	USP 5164194 Patent Assignment Abstract of Title	MPAT 000187-000188				
431	USP 5164194 Maintenance Fee Statement	MPAT 000189-000191				
432	Azelastine Assignment Document from Hettche	MPAT 000192-000194				
433	ASTA Conveyance Document re Name Change	MPAT 000195-000196				
434	ASTA Conveyance Document re Name Change	MPAT 000197-000206				
435	Viatis Conveyance Document re Assignment	MPAT 000207-000213				
436	USPTO Notice of Recordation of Assignment Document	MPAT 000214-000223				
437	MedPointe Conveyance Document re Security Agreement	MPAT 000224-000230				
438	Hettche Questionnaire					
439	Hettche Deposition Transcript					
439A	English Translation of Hettche Deposition Transcript					
440	Szelenyi Questionnaire					
441	Szelenyi Deposition Transcript					
441A	English Translation of Szelenyi Deposition Transcript					
442	Engel Questionnaire					
443	Engel Deposition Transcript					
443A	English Translation of Engel Deposition Transcript					
444	Cirillo, Pharmacology and Therapeutic Use of Antihistamines, Am J. Hosp Pharm 33: 1200-1207 (Nov) 1976.	AS-MEDA 000040-000046				

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PTX	Description	Bates Range	PDX	Admission		Date Admitted
				No Obj.	Objection Basis	
445	Hunnus Pharmazeutisches Wörterbuch	AS-MEDA 000242-000244				
445A	English Translation of Hunnius Pharmazeutisches Wörterbuch					
446	Romp Chemie Lexikon	AS-MEDA 000245-000246				
446A	English Translation of Romp Chemie Lexikon					
447	27. Jan. 1986 Notiz für Herrn Dr. Hettche	AS-MEDA 004168-004169				
447A	English Translation of 27. Jan. 1986 Notiz für Herrn Dr. Herbst from Dr. Hettche					
448	Asta Pharma Report re "Azelastrine HCl 0.1%: Effects on ciliary activity of guinea pig nasal mucosa after local administration" (1992)	AS-MEDA 000691-000692				
449	Fisher, Contact Dermatitis from Topical Medicaments (1982).	AS-MEDA 001214-001222				
450	Treatment of Seasonal Perennial Rhinitis, British Medical Journal 283: 1981.	AS-MEDA 001288-001290				
451	Achteirath-Tuckermann, Experimental Studies on Acute and Chronic Action of Azelastrine on Nasal Mucosa in Guinea Pigs, Rats and Dogs	AS-MEDA 001962-001966				
452	Reynolds, Martindale: The Extra Pharmacopoeia	AS-MEDA 002009-002011				
453	Biopharmazie	AS-MEDA 005739-005741				
453A	English Translation of Biopharmazie					
454	13.08.90 Memo from Hettche to Herrn and Herbst	AS-MEDA 007806-007806				
454A	English Translation of 13.08.90 Memo from Hettche to Herrn and Herbst					
455	Externe Therapie Von Hautkrankheiten	AS-MEDA 008489-008490				
455A	English Translation of Externe Therapie Von Hautkrankheiten					
456	Textbook Of Dermatology Volume One Third Edition	AS-MEDA 008491-008494				
457	Intentionally left blank					

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PTX	Description	Bates Range	PDX	Admission No Obj.	Objection Basis	Date Admitted
458	Patent No. 1,377,231	AS-MEDA 009862-009873				
459	12.08.87 Memo from Hettche to Ulbrich re Azelastin Nasenspray	AS-MEDA 009938-009938				
459A	English Translation of 12.08.87 Memo from Hettche to Ulbrich re Azelastin Nasenspray					
460	Medpointe Spreadsheets re Astelin Monthly NRx, TRx, TRx EU (1/97-6/06)	AS 006780-006833				
461	Medpointe Spreadsheet re Astelin Monthly Net Sales (1/97-5/07)	AS 007951-007954				
462	Medpointe Spreadsheet re Astelin Monthly TRx (7/06-5/07)	AS 007955-007957				
463	Medpointe Spreadsheet re Astelin Monthly TRx EU (7/06-5/07)	AS 007958-007960				
464	Medpointe Spreadsheet re Astelin Monthly NRx (7/06-5/07)	AS 007961-007963				
465	Medpointe Spreadsheet re Astelin Monthly TRx (6/07-11/07)	AS 008695				
466	Medpointe Spreadsheet re Astelin Monthly Net Sales (1/97-12/07)	AS 008696-008697				
467	Influence of Azelastine, Administered After Antigen Challenge, on Acute Lung Anaphylactic Responses in Guinea Pigs - PH-85-5	AZ 004191-004203				
468	Berger, "Impact of azelastine nasal spray on symptoms and quality of life compared with cetirizine oral tablets in patients with seasonal allergic rhinitis" Annals of Allergy 97 (2006), DX 48					
469	Byrn, Graber and Midland. "Comparison of the Solid and Solution Conformation of Methallylamine, Tripelennamine...", J. Org. Chem., Vol. 41, No. 13, 1976					
470	Morris et al. "Advances in Pharmaceutical Materials and Processing," PSIT Vol. 1, No. 6, September 1998.					
471	Remington's excerpt (1985) - pg. 441					
472	Apotex ANDA excerpts	A 000956-000967; A 001025-001052; A 001399-001405				
473	Bioequivalency Amendment	A 007932-007937				
474	The Random House Dictionary; p. 71 (definition of ampoule)		200			
475	Black's Medical Dictionary; p. 31 (definition of ampoule)		201			



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PTX	Description	Bates Range	PDX	Admission		Date Admitted
				No Obj.	Objection Basis	
476	The Wiley Encyclopedia of Packaging Technology; pp. 16-20, 506-509, 720 ("ampuls and vials", "pharmaceutical packaging")		202			
477	Chand, N. "Inhibition of Leukotriene (SRS-A)-Mediated Allergic Bronchospasm by Azelastine, a Novel Orally Active Antiasthmatic Drug."		203			
478	Diamantis, W. "Inhibition of IgE-mediated Passive Cutaneous Anaphylaxis (PCA) by Azelastine in Rat."		204			
479	Chand, N. "Inhibition of Acute Bronchial Anaphylaxis by Azelastine (AZ) in Aerosol-Sensitized Guinea Pig (GP) Asthma Model."		205			
480	Chand, N. "Inhibition of Leukotriene (SRS-A)-Mediated Acute Lung Anaphylaxis by Azelastine in Guinea Pigs."		206			
481	Chand, N. "Inhibition of Antigen-Induced Airway Hyperreactivity (IAH) to Cold Provocation by Azelastine and Selected Antiasthmatic Drugs in Rat Isolated Tracheal Segments."		207			
482	Chand, N. "Inhibition of 5-Hete... Synthesis by Azelastine and its d- and l-isomers in Rat Mixed Peritoneal Cells."		208			
483	Apotex ANDA excerpts	A 000965-000967; A 001400				
484	Aerosols in Medicine excerpts	A 006221-006222; A 006230-006249; A 006311				
485	Ansel, "Introduction to Pharmaceutical Dosage Forms"	A 000194-000195; A 000208-000212				
486	Remington's excerpt (1985) - pp. 82, 1500					
487	Remington's excerpt (1970)	A 006444-006445; A 006459-006481				
488	US Pharmacopeia re overages; pp. 1137 - 1138					
489	Orgel et al., Comparison of Intranasal Cromolyn Sodium and Oral Terfenadine for Allergic Rhinitis (abstract) Journal of Allergy and Clinical Immunology 1988; 81:351					

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PTX	Description	Bates Range	PDX	Admission		Date Admitted
				No Obj.	Objection Basis	
490	Meltzer et al., An Open Label Study of Azelastine Nasal Spray in the Treatment of Nasal Congestion in Patients with Seasonal Allergic Rhinitis (abstract) Ann. Allergy Asthma Immunol. 2004; 92: 137-138					
491	Meltzer et al., Azelastine nasal spray significantly improves health related quality of life compared to cetirizine tablets in patients with seasonal allergic rhinitis (SAR). (abstract) J. Allergy Clin. Immunol. 2006; 117:S324					
492	Bronsky et al., Cardiac safety of azelastine following 8 weeks of intranasal administration (abstract) J. Allergy Clin. Immunol. 1997; 99:S445					
493	Meltzer et al., Evaluation of the safety/efficacy of azelastine nasal spray in seasonal allergic rhinitis (abstract) Clin. Exper. Allergy 1990; 20: 100					
494	Weiler et al., A Safety and Efficacy Evaluation of Azelastine (AZ) Nasal Spray (NS) in Seasonal Allergic Rhinitis (SAR) (abstract) J. Allergy Clin. Immunol. 1991; 87:219					
495	Allergic Diseases: Diagnosis and Management, Fourth Edition. Ed. Patterson. Philadelphia: J.B. Lippincott Company, 1993. 242-49					
496	The Merck Index, 10th Edition. Ed. Windholtz. Rahway: Merck & Co. Inc., 1983. 150					
497	Handbook of Nonprescription Drugs, 7th Edition (1982) (Title page; Copyright page; Table of Contents; pp. 166-169 and 428-430)					
498	Allergic Diseases, 2d Edition. Ed. Patterson. Philadelphia: J.P. Lippincott Company, 1980. 179-203					
499	Allergic Diseases, 3d Edition. Ed. Patterson. Philadelphia: J.P. Lippincott Company, 1985. 64-101, 206-231, 374-407, 758-93					
500	Allergy Principles and Practice, 2d Edition. Ed. Middleton, Reed, Ellis. St. Louis: C.V. Mosby Company, 1983. 118-47, 270-303, 382-435, 574-633, 770-803, 1100-1143					

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PTX	Description	Bates Range	PDX	Admission		Date Admitted
				No Obj.	Objection Basis	
501	Bousquet, J. "ARIA in the pharmacy: management of allergic rhinitis symptoms in the pharmacy." Allergy, Vol. 59, 2004: 373-387					
502	Dykewicz, MS. "Executive Summary of Joint Task Force Practice Parameters on Diagnosis and Management of Rhinitis." Annals of Allergy. Vol. 81, 1998: 463-468					
503	Garbe, E. "Inhaled and nasal glucocorticoids and the risks of ocular hypertension or open-angle glaucoma." Allergy. Volume 277, 1997: 722-727					
504	Grossman J. "Onset of Action and Patient Acceptance of Azelastine in a Nasal Spray formulation." Abstracts from XVIth International Congress of Allergy and Clinical Immunology. 1997					
505	Meltzer, E.O. "A dose-ranging study of the efficacy and safety of azelastine nasal spray in the treatment of seasonal allergic rhinitis with an acute model." J Allergy Clin Immunol. Volume 94, 1994: 972-980					
506	Meltzer, E.O. "A dose-response study of the bronchodilator action of azelastine in asthma." J Allergy Clin Immunol. volume 79, 1987: 893-899					
507	Meltzer, E.O. "A step approach to the clinical management of allergic rhinitis: prescription and over-the-counter reference summary." Managed Care Interface. Volume 12, 1999:70-77					
508	Meltzer, E.O. "An overview of current pharmacotherapy in perennial rhinitis." J Allergy Clin Immunol. Volume 95, 1995:1097-1110					
509	Meltzer, E.O. "Beclomethasone dipropionate nasal aerosol spray in allergic rhinitis: a comparison of three delivery systems." Ann Allergy. Volume 55, 1985:802-804					
510	Meltzer, E.O. "Double-blind assessment of azelastine in the treatment of perennial allergic rhinitis." Ann Allergy. Volume 73, 1994: 141-146					

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PTX	Description	Bates Range	PDX	Admission		Date Admitted
				No Obj.	Objection Basis	
511	Meltzer, E.O. "Effects of azelastine nasal spray on individual rhinitis symptoms." (abst) Ann Allergy Asthma Immunol. Volume 78, 1997:143					
512	Meltzer, E.O. "Evaluation of symptom relief, nasal airflow, nasal cytology, and acceptability of two formulations of flunisolide nasal spray in patients with perennial allergic rhinitis." Ann Allergy. Volume 64, 1990:536-540					
513	Meltzer, E.O. "Evaluation of the optimal oral antihistamine for patients with allergic rhinitis." May Clin Proc. Volume 80, 1995:1170-1176					
514	Meltzer, E.O. "Intranasal steroids: managing allergic rhinitis and tailoring treatment to patient preference." Allergy and Asthma Proc. Volume 26, 2005: 445-451					
515	Meltzer, E.O. "Olopatadine HCl nasal spray is effective and safe for the treatment of seasonal allergic rhinitis." (abst) Ann Allergy Asthma Immunol. Volume 92, 2004:103					
516	Meltzer, E.O. "Pharmacological treatment options for allergic rhinitis and asthma." Clin Exp Allergy. Volume 28, 1998:27-36					
517	Meltzer, E.O. "Rhinitis not just hay fever." Patient Care. Volume 23, 1989:168-184					
518	Meltzer, E.O. "The current outlook on chronic allergic rhinitis." J Respir Dis. Volume 6, 1985:100-123					
519	Opatowsky, I. "Intraocular pressure elevation associated with inhalation and nasal corticosteroids." Ophthalmology. Volume 102, 1995:177-179					
520	"Steroid-Free Astelin (R) Nasal Spray (R) Demonstrated Seasonal Allergy Symptom Improvement Within 15 Minutes in Clinical Study." www.medicalnewstoday.com. Accessed on 06-28-2007.	ASC 000229-000230				

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 Plaintiff's Trial Exhibits

PTX	Description	Bates Range	PDX	Admission		Date Admitted
				No Obj.	Objection Basis	
521	Letter from Hankin to Carter-Wallace re Astelin Marketing	A 006439-006443				
522	Aerosols in Medicine: Principles, Diagnosis and Therapy. Ed. Moren, newhouse, and Dolovich. Amsterdam:Elsevier, 1985. Pgs: Cover, Title, Copyright (A06220-22), xi-xvii (A06223-29), 1-20 (A06230-49), 53-76 (A06250-73), 123-147 (A06274-98), 193-197, 198-199 (A06299-6300), 200-206, 207-209 (A06301-03), 210-217, 251-262 (A06304-05), 263-267, 268-272 (A06306-10), 273-282, 283-284 (A06311-12), 285-287, 289-293 (A06313-17), 294-306, 307-308, (A06318-19), 309-312					
523	Hardy, JG "Intranasal Drug Delivery by Spray and Dros." J. Pharm Pharmacol. Vol. 37, 1985:294-297					
524	Defendants' Deposition Exhibit 53A					
525	Defendants' Deposition Exhibit 53B					
526	Stipulated Findings of Fact					
527	Black's Medical Dictionary, pp. 540, 589.					

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PTX	Description	Bates Range	PDX	Admission		Date Admitted
				No Obj.	Objection Basis	
528	Random House Dictionary; pp. 102, 222, 326, 431, 456, 559, 620, 1194, 1651.					
529	McGraw-Hill Dictionary of Chemical Terms. Ed. Parker. New York: McGraw-Hill, 1985. pp. 31, 152, 400.					
530	Grant and Hackh's Chemical Dictionary; pp. 373.					
531	Ansel, "Introduction to Pharmaceutical Dosage Forms." (1985); pp. 325, 338.					
532	Physician's Desk Reference (1987); p. 928.					
533	ANDA-related Correspondence	A 007912-007921; A 007941-008131; A 008147-008153; A 008292-008320				
534	Deficiency Letter	A 007932-007940				

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PTX	Description	Bates Range	PDX	Admission		Date Admitted
				No Obj.	Objection Basis	
535	Response to Deficiency Letter	A 008379-008596				
536	ANDA No. 77-954	A 000942-003287; A 005060-005065, A 005146-005151, A 005247-005249, A 005252, A 005255				
537	Excerpt from Expert Report of Dr. Bym reviewed by Dr. Meltzer and Dr. Dalby					
538	Excerpt from Expert Report of Dr. Bym reviewed by Dr. Dalby					
539	Excerpt from Expert Report of Dr. Meltzer reviewed by Dr. Dalby					
540	Excerpt from Expert Report of Dr. Dalby reviewed by Dr. Bym					
541	Excerpt from Expert Report of Dr. Meltzer reviewed by Dr. Bym					
4000	Physical Exhibits					
5000	Demonstratives					

## **EXHIBIT 15**



EXHIBIT 15

**DEFENDANTS' LIST OF TRIAL EXHIBITS**

Attached is a list of exhibits that Defendants intend to offer at trial.

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

MEDPOINTE HEALTHCARE INC., )  
 )  
 Plaintiff/Counter-Defendant, )  
 )  
 C.A. No. 06-164 (SLR) )  
 )  
 v. )  
 )  
 APOTEX INC. and APOTEX CORP., )  
 )  
 Defendants/Counter-Plaintiffs. )

**DEFENDANTS TRIAL EXHIBIT LIST**

TRIAL EXHIBIT NUMBER	DATE	DESCRIPTION	WITNESS	ADMIT	OBJECTION
* 1	03/00/50	S.M. Feinberg, "Drugs In Allergy," Trans. Amer. Acad. Of O&O, Vol. 124 (March-April 1950), pp. 283-286 (A00085 - A00088). Meltzer 11			
* 2	05/00/50	E.L. Keeney, "Medical Progress: Histamine and the Antihistaminic Drugs," California Medicine, Vol. 72, No. 5, pp. 377-389 (May 1950)(A00089-A00104).			
3	00/00/69	R. Barkman, M. Germanis, G. Karpe and A.S. Malmberg, "Preservatives In Eye Drops," Acta Ophthalmologica, Vol 47, No. 1, pp. 461-475 (1969)(A00105 - A00120).			
* 4	00/00/70	A.J. Bentley and R.T. Jackson, "Changes in the Patency of the Upper Nasal Passage Induced by Histamine and Antihistamines," The Laryngoscope, Vol. 80, No. 12, pp. 1859-1870 (1970)(A00121-A00132).			

**Keywords:** *work engagement, organizational commitment, turnover intentions, organizational citizenship behaviors, organizational identification, organizational trust, organizational justice, organizational support, organizational identification, organizational trust, organizational justice, organizational support*

**\* EXHIBIT ALSO APPEARS ON PLAINTIFF'S EXHIBIT LIST**

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<b>*</b> 5	11/00/74	J.A. Blue, "Current Concepts of Allergy of the Eye," Annals of Allergy, Vol. 33, pp. 267-273 (November 1974)(A00139-A00146).			
<b>*</b> 6	04/15/75	U.S. Patent No. 3,878,217 issued April 15, 1975 (A00147 - A00156).			
<b>*</b> 7	00/00/76	D.S. Pearlman, "Antihistamines: Pharmacology and Clinical Use," Drugs, Vol. 12, No. 1, pp. 258 - 273 (1976)(A00157-A00174).			
<b>*</b> 8	00/00/76	A.A. Kassem, E. Nour El-Din, N.M. Mursi, A. Abd Elbary and N. Foda, "Formulation and Stabilization of Antazoline Hydrochloride Nasal Drops," Bulletin of the Faculty of Pharmacy, Vol. 15, No. 2, pp. 161-175 (1976)(A00175 - A00193).			
<b>*</b> 9	00/00/76	H.C. Ansel, "Chapter 11 - Ophthalmic Preparations" and "Chapter 12 - Ear, Nose, and Topical Preparations," Introduction to Pharmaceutical Dosage Forms, 2nd Ed., pp. 333-349, (Lea & Febiger - Philadelphia)(1976)(A00194 - A00212).			
<b>*</b> 10	08/00/78	L.H. Hamilton, "Effect of Topical Decongestants on Nasal Airway Resistance," Current Therapeutic Research, Vol. 24, No. 3, pp. 261-268 (August 1978)(A00213 - A00221).			
<b>*</b> 11	00/00/79	K. Tasaka and M. Akagi, "Anti-allergic Properties of a New Histamine Antagonist, 4-(p-Chlorobenzyl)-2-[N-methyl-perhydroazepinyl-(4)]-1-(2H)-phthalazinone Hydrochloride (Azelasine)," Arzneimittel Forschung/Drug Research, Vol. 29, No. 3, pp. 488-493 (1979)(A00222 - A00229).			
<b>*</b> 12	00/00/79	Physicians Desk Reference, 33rd Edition, pp. 873, 892, 1512 and 1851 (1979)(A00230 - A00235).			
<b>*</b> 13	00/00/80	R.R. File and T.F. Patton, "Topically Applied Pilocarpine," Archives of Ophthalmology, Vol. 98, No. 1, pp. 112-115 (January 1980)(A00236-A00241).			

14	*	00/00/80	K. Tatsumi, T. Ou, H. Yamada and H. Yoshimura, "Studies on Metabolic Fate of a New Antiallergic Agent, Azelastine (4-(p-Chlorobenzyl)-2-[N-Methylperhydroazepinyl-(4)]-1-(2H)-Phthalazinone Hydrochloride)," Japan J. Pharmacol. Vol. 30, pp. 37-48 (1980)(A00242-A00253).			
15	*	00/00/80	Physicians' Desk Reference for Nonprescription Drugs, First Edition, pp. 502-03, 506, 522, 539, 553, 616, 637-38, 646, 654-55 (1980)(A00276 - A00289).			
16	*	00/00/81	W. Diamantis, J.E. Harrison, J. Melton, J.L. Perhach, Jr., and R.D. Sofia, "In Vivo and In Vitro H1 Antagonist Properties of Azelastine," Vol. 23, No. 3, The Pharmacologist (1981), p. 149 (A00290-A00293).			
17	*	03/03/81	U.S. Patent No. 4,254,129 issued March 3, 1981 (A00294 - A00304).			
18	*	09/00/81	S.W. Lam, R.C. Meyer and L.T. Takahashi, "Determination of Thimerosal in Ophthalmic Solutions by Redial Compression Separation HPLC," Journal of Parenteral Science and Technology, Vol. 35, No. 5, pp. 262-265 (September-October 1981)(A00305 - A00308).			
19	*	00/00/82	W. Diamantis, N. Chand, J.E. Harrison, J. Pillar, J.L. Perhach, Jr. and R.D. Sofia, "Inhibition of Release of SRS-A and Its Antagonism by Azelastine (A), An H1 Antagonist-Antiallergic Agent," The Pharmacologist, 24, No. 82, p. 200 (1982)(A00325-A00328).			
20	*	02/00/82	U.S. Patent No. 4,313,931 issued February 2, 1982 (A00329 - A00339).			
21		09/00/82	C. Secher, J. Kirkegaard, P. Borum, A. Maansson, P. Osterhammel and N. Mygind, "Significance of H1 and H2 receptors in the human nose: rationale for topical use of combined antihistamine preparations," The Journal of Allergy and Clinical Immunology, Vol. 70, No. 3, pp. 211-218 (September 1982)(A00340-A00349).			

22	*	00/00/82	R.C. Kersten, "Ophthalmic Drugs," Primary Care: Clinics in Office Practice, Vol. 9, No. 4, pp. 743-756 (December 1982)(A00350 – A00365).			
23	*	00/00/82	J. Kirkegaard, C. Secher, and N. Mygind, "Effect of the H1 Antihistamine Chlorpheniramine Maleate on Histamine-Induces Symptoms in the Human Conjunctiva," Allergy, Vol. 37, pp. 203-208 (1982)(A00366-A00371).			
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312	09/07/90		Letter from Dr. Hettche & Dr. Molliere to Dr. Gordziel re: Enclosure of publication (AS0002995- AS0003013)			
313			Memorandum of Record: Telephone contact with Dr. Hettche, Manager Formulations, Degussa Pharma, Germany (AS0003146- AS0003147)			
314	04/28/89		Memorandum from M. Bielant to Dr. Diamantis & Dr. Gordziel re: ASTA document – Azelastine HCL (AS0003184- AS0003193)			
315	04/16/97		Minutes: Azelastine project Team Meeting No. 43 (AS0004108 – AS0004136)			
316	07/02/92		Letter from E. Matarese to B. Wilson re: Enclosure of test results (AS0003447- AS0003468)			
317	01/05/90		Memorandum from Dr. Wang to Dr. Bodin re: Droplet Size Pattern Nasalide Nasal Spray in Syntex and Valois Metered Dose Nebulizers (AS0003558- AS0003560)			
318	12/14/89		Memorandum from Dr. Wang to Dr. Bodin re: Droplet Size Pattern Nasalide Nasal Spray in Syntex and Valois Metered Dose Nebulizers (AS0003572- AS0003577)			
319	11/20/91		Amendment to research report (AS0004236- AS0004237)			
320	01/03/91		Wallace Laboratories report: Formula Rationale for Azelastine Hydrochloride Nasal Solution 0.1% w/v (AS004850-AS004860)			
321	11/24/92		Letter from D. Auslander to Dr. Hettche re: topics to be discussed on December 4 <sup>th</sup> . (AS0005080 – AS0005082)			
322	10/24/90		Wallace Laboratories report: Solubility of Azelastine Hydrochloride in Azelastine Hydrochloride Nasal Solution (AS0005433- AS0005437)			
323	09/24/90		Wallace Laboratories report: Validation of the Liquid Droplet Sizing Method for Azelastine Hydrochloride 0.1% Nasal Spray (Valois Pumps) Using the Malvern Particle Analyzer (AS0005452- AS0005476)			

324	00/00/88	A. Mitra, S. Gordziel, "Characterization of Hydration / Solvation Characteristics of Azelastine Hydrochloride," Drug Development and Industrial Pharmacy, 14(7) 953-975 (1988) (AS0005732- AS0005754)			
325	08/14/84	Wallace Laboratories report: Azelastine Hydrochloride: pH vs. Solution Stability (AS0005799- AS0005805)			
326	09/25/92	Wallace Research & development Department Presentation to Scientific Advisory Board; September 25, 1992 (AS0006195-0 AS0006200)			
327		Azelastine Pharmacological Profile (AS0006209- AS0006213)			
328	06/26/90	ASTA Pharma report: Azelastine Investigational Drug Brochure (AS0006334- AS0006415)			
329	07/27/90	Letter from I. Szelenyi to D. Sofia (AS0006416)			
330	07/06/92	Memorandum from M. Biela re: Azelastine-Publications List (AS0006485- AS0006535)			
331	02/13/90	Amendment No. 1 to ASTA Pharma report LC-5505 (AS0006544- AS0006546)			
332	07/11/89	Memorandum from K. Bielat to D. Fields, J. Freitag, S. Gordziel & J. Perach re: ASTA documents- Azelastine (AS0006586 – AS0006589)			
333	08/24/88	Memorandum from N. Ivins to Dr. McGee re: GLP Audit of the Final Draft report (AS0006614 – AS0006640)			
334	0707/89	Wallace Laboratories report: Six –Month Intranasal Toxicity study of Azelastine Hydrochloride in the Albino rat (AS0006658- AS0006668)			
335	01/31/91	ASTA Pharma report: A TwoWeek Comparative Study of The Safety and Efficacy of Azelastine Nasal Spray in the Management of Seasonal Allergic Rhinitis (AS0006703 – AS0006714)			
336	03/09/90	ASTA Pharma report: Protection of Azelastine.HCL nasal spray against nasal alterations induced by aallergen challenge (AS0006722- AS0006726)			
337	06/30/90	ASTA Pharma report: Inhibition of histamine –induced nasal hypersecretion by azelastine following local application (AS0006727- AS0006747)			

338	11/18/91	Listing of ASTA's clinical studies (AS0006765- AS006769)		
<b>*</b> 339		Astelin net sales; January 1997- June 2006 (AS0006777- AS0006779)		
<b>*</b> 340		AS0006780- AS0006833		
341	12/01/03	Letter from R. Fosko to the FDA re: Request for clarification (AS0006871- AS0006877)		
342	03/03/04	Facsimile from the FDA to R. Fosko re: February 3, 2004 teleconference (AS0006900- AS0006903)		
<b>*</b> 343	08/16/02	Assignment and Assumption Agreement (AS0007016- AS0007027)		
<b>*</b> 344	11/01/97	Schedule E: Assignment and and Assumption Agreement (AS0007028- AS0007033)		
<b>*</b> 345	11/01/97	Exhibit B: License Agreement (AS0007034- AS0007036)		
<b>*</b> 346	11/01/97	Exhibit : Amendment to Azelastine License Agreement (AS0007037-AS0007038)		
<b>*</b> 347	07/31/96	Letter from D. Black to DR. Engel re: August 16, 1982 License Agreement (AS0007039- AS0007040)		
<b>*</b> 348	04/11/01	Amendment to August 16, 1982 License Agreement (AS0007041- AS0007042)		
<b>*</b> 349	05/17/02	Interest Purchase Agreement (AS0007045- AS0007067)		
<b>*</b> 350	05/17/02	Exhibit A: Agreement (AS0007068- AS0007079)		
<b>*</b> 351	05/17/02	Schedule III: Patent Assignment (AS0007080- AS0007085)		
<b>*</b> 352		Schedule IV: 07/31/96 letter to Dr. Engel (AS0007086- AS0007088)		

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EXHIBIT ALSO APPEARS ON PLAINTIFF'S EXHIBIT LIST



353	*	08/16/92	License Agreement between Homburg & Degussa (AS007908- AS0007950)			
354		08/30/90	Meeting minutes of the 04/19-20/90 Wallace/ASTA joint scientific meeting (AS0007124- AS007171)			
355	*	02/27/87	Telefax from D. Fields to Dr. Engel re: Enclosure of meeting minutes (AS0007208- AS0007235)			
356		03/29/88	Meeting minutes of the 11/30-12/01/87 Wallace/ASTA joint scientific meeting (AS0007236- AS0007274)			
357		04/22/92	Meeting minutes of the 10/31-11/01/91 Wallace/ASTA joint scientific meeting (AS0007281- AS0007333)			
358		08/18/89	Highlight of the July 16, 1989 Developmental Research Azelastine Project Meeting (AS0007419- AS0007423)			
359		05/10/89	Memo from E. Bohrer re: May 3, 1989 Developmental Research Azelastine Project meeting (AS0007424- AS0007444)			
360		02/25/87	Meeting minutes (AS0007445- AS0007471)			
361		01/24/06	Apotex's Paragraph IV Letter (AS0007855- AS0007883)			
362		10/02/89	Memorandum from Dr. Gordziel & Dr. Morko re: ASTA Pharma Scientific Meeting 09/14-15/89) (AS0007890 -- AS0007895)			
363	*		Astelin net sales; January 1997- May 2007 (AS0007951- AS0007954) (DDX 57 Hostler)			
364	*		Data Report from IMS Health re: Total Astelin prescriptions (AS0007955- AS0007957) (DDX 60 Hostler)			
365	*		Data Report from IMS Health re: Total Astelin Prescriptions (AS0007958- AS0007960) (DDX 59 Hostler)			
366	*		Data Report from IMS Health re: New Astelin Prescriptions (AS0007961- AS0007965) (DDX 58 Hostler)			
367		12/18/01	Master Services Agreement between MedPointe & Wallace (AS0007966- AS0007983)			
368		08/05/02	Letter from MedPointe to Sepracor, Inc. re: proposed co promotion arrangement (AS0007984- AS0008047)			

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EXHIBIT ALSO APPEARS ON PLAINTIFF'S EXHIBIT LIST

369	06/08/98	Agreement between Carter-Wallace and Syncom (AS0008048- AS0008075)			
370	03/31/98	Wallace Laboratories – Financial Statements for the 12 <sup>th</sup> Month ending 03/31/98 (AS0008076- AS0008255)			
371	03/01/01	Wallace Laboratories – Financial Statements for the 12 <sup>th</sup> Month ending 03/01/01 (AS0008256- AS0008255)			
372	03/31/04	Medpointe Pharmaceuticals Financial Statements for the Twelve Months ending 03/31/04 (AS0008428 – AS0008620)			
373		New Drug Application: ASN000000001 – ASN00221537			
373A	03/26/91	Letter from Wallace laboratories to the FDA re: NDA20114 (ASN000000006 – ASN000000009)			
373B		NonClinical Pharmacology and Toxicology Summary (ASN00000353 – ASN04000437)			
373C	00/00/80	M. Okuda, et al., Oto-Rhino-Laryngology Tokyo, Vol 23, Suppl. 6, pp. 441-461 (1980)(A00254–A00275)(with English summary provided by Carter-Wallace to the FDA at 08 35301 – 08 35313) See ASN00074575-ASN00074587.			
374		Initial New Drug Application: ASI0000000001 – ASI00005368			
374A		Investigator's Brochure (ASI000000023 – ASI0000000147)			
374B	01/22/90	Letter from Wallace Laboratories to the FDA (ASI00003249 – ASI00003399)			
374C		Item C from the General Investigational Plan (ASI00004058 – ASI00004060)			
374D		Item B from the General Investigational Plan (ASI00004087 – ASI00004106)			
375		Initial New Drug Application for Azelastine Tablets: AT100000001 – AT100002428			
375A	09/23/80	Wallace Laboratories Report: AT100000919 – AT100000947)			
376	11/16/90	Asta Pharma Report, "Comparison of efficacy and tolerability of azelastine nasal spray, azelastine tablets and astemizole in the treatment of seasonal allergic rhinitis," (MPAT0000490 – MPAT000494)			

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377	*	1996	R.J. Davies, A.C. Bagnall, R.N. McCabe, M.A. Calseron, and H.J. Wang, "Antihistamines: topical v.s oral administration," Clinical Experimental Allergy, 1996 Voil. 26 Suppl 3, ppgs. 11-17 (including front cover and copyright pages) (ASC0000062 – ASC0000070)			
378	*	06/00/94	W.W. Storms, D.S. Pearlman, P.O. Chervinsky, J. Grossman, P.C. Halverson, J.J. Freitag and M.D. Widlitz, "Effectiveness of Azelastine Nasal Solution in Seasonal Allergic Rhinitis," ENT, Vol 73 No. 6 (June 1994), pp. 382-394 (including front cover and copyright page) (ASC0000169-ASC0000179)			
379	*	10/00/97	D.Wang, J. Smitz, M. De Waele, and P. Clement, "Effect of Topical Applications of Budesonide and Azelastine on Nasal Allergen Challenge during Pollen Season," Int Arch Allergy Immunol 1991; 114:: 185-192 (October 1997) (including front cover and copyright page) (ASC0000203 – ASC0000212)			
380	*	02/26/07	Medical News Today: Steroid-Free Astelin® Nasal Spray® Demonstrated Seasonal Allergy Symptom Improvement Within 15 Minutes in Clinical Study (ASC0000229- ASC0000230)			
381		2007	T. Lee, A. Simon, " Meta-Analysis of Azelastine Nasal Spray for the Treatment of Allergic Rhinitis, Pharmacotherapy 2007; 27 (6) :852-859) (ASC0000231 – ASC0000238) (DDX 49)			
382		12/20/85	A. Warner, " Effects of Methylxanthines on Airway Mucociliary Function," The American Journal of Medicine Volume 79 (suppl 6A) (A08343- A08348)			
383			Product insert for Migranal (A08349- A08350)			
384		06/22/86	U.S. Patent 4,602,099 (A08351- A08358)			
385		00/00/82	Handbook of Nonprescription Drugs 7 <sup>th</sup> edition (cover page, table of contents, pps 166- 169; 428 – 430) (A08359- A08371)			
386		02/26/85	U.S. Patent 4,501,893 (A08372- A08378)			

387	00/00/93	X. Su, A. Po, "The effect of some commercially available antihistamine and decongestant intra-nasal formulations on ciliary beat frequency," Journal of Clinical Pharmacy and Therapeutics (1993) 18, 218-222 (A08339- A08342)		
388		Curriculum Vitae of Maureen D. Donovan, Ph.D.		
389		Curriculum Vitae of Ronald H. Smith		
390		Curriculum Vita of Howard J. Schwartz M.D.		
391	03/13/06	Amended Complaint		
392	04/14/06	Answer to the Amended Complaint		
393	06/16/07	Rule 16 Scheduling Order		
394	04/18/07	Deposition transcript of Naresh Chand		
394A	02/27/84	N. Chand, "Inhibition of Allergic and Nonallergic Histamine Secretion by Azelastine, Its Putative Metabolites and Analogs in Rat Peritoneal Mast Cells and Rabbit Mixed Leukocytes (Basophils), Wallace Laboratories, Pharmacology, PH-84-6, February 27, 1984 (ASN00003646 – ASN00003665) (PDX 1 Chand)		
394B		Wallace Laboratories Report (ASN00003727 – ASN00003744) (PDX 2 Chand)		
3943C	04/02/07	Letter from S. Benson to LaSalle Process Servers (DDX 14 Chand)		
394D	05/28/74	U.S. Patent No. 3,813,384 issued May 28, 1974 (A00133 – A00138)(A06652 – A06657). * (DDX 15 Chand, Meltzer 5)		
394E	11/17/92	U.S. Patent 5,164,194 issued November 17, 1992 (A00763 – A00768) (DDX 16 Chand)		
394F	11/03/87	U.S. Patent No. 4,704,387 issued November 3, 1987 (A00564 – A00569)(A06646 – A06651) (DDX 17 Chand)		
394G	04/11/07	PUB MED Printout (DDX 18 Chand)		
394H	00/00/80	N. Chand, "Is Airway Hyperactivity in Asthma Due to Histamine H2 –Receptor Deficiency?" Medical Hypothesis 6: 1105-1112, 1980. (CH000066- CH000073). (DDX 19 Chand)		

394I	00/00/83	N. Chand, J. Pillar, W. Diamantis, J. Perhach, D. Sofia, "Inhibition of Calcium Ionophore (A23187) Stimulated Histamine Release From Rat Peritoneal Mast Cells By Azelastine: Implications for its Mode of Action," European Journal of Pharmacology 96 (1983) 277-273, (CH00074 - CH00080). (DDX 20 Chand)			
394J	00/00/84	D. Fields, J. Pillar, W. Diamantis, J. Perhach, D. Sofia, N. Chand, "Inhibition by Azelastine of non allergic histamine release from rat peritoneal mast cells," J Allergy Immunol 73:400-403 1984. (CH00081- CH00084) (DDX 21 Chand)			
394K	00/00/84	N. Chand, W. Diamantis, J. Pillar, D. Sofia, " Inhibition of allergic and non-allergic histamine secretions from rat peritoneal mast cells by calcium antagonists," BR. J. Pharmac. (1984) 899-902. (CH00085- CH00088). (DDX 22 Chand)			
394L	00/00/85	N. Chand, J. Pillar, W. Diamantis and R.D. Sofia, "Inhibition of IgE-mediated allergic histamine release from rat peritoneal mast cells by azelastine and selected antiallergic drugs," Agents and Actions, Vol. 16, No. 5, pp. 318-322 (1985)(A00885 - A00889) (A06062-A06066). (DDX 23 Chand)			
394M	09/21/84	N. Chand, J. E. Harrison, S. Rooney, R. Sofia and W. Diamantis, "Inhibition of Passive Cutaneous Anaphylaxis (PCA) by Azelastine: Dissociation of its Antiallergic Activities from Antihistaminic and Antiserotonin Properties", Int. J. Immunopharmacology, Vol. 7 No. 6 pp 833 - 838 (DDX 24 Chand)			
394N	00/00/86	N. Chand, K. Nolan, W. Diamantis, J. Perach, D. Sofia, "Inhibition of Leukotriene (SRS-A) Mediated Acute Lung Anaphylaxis by Azelastine in Guinea Pigs," Allergy 1986,41,473-478. (CH0100- CH0105) (DDX 25 Chand)			
394O	02/21/07	N. Chand, K. Nolan, W. Diamantis and R.D. Sofia, "Effect of Aerosolized Azelastine on Acute Lung Anaphylaxis in Guinea Pigs (GP) Sensitized by Two Different Procedures," The Pharmacologist, Vol. 27, No. 1 (1985)(Abstract 76)(DDX 26Chand) CH0111 - CH0113)(A05995)			



395		Article: Bestehen dosisabhängige Wirkungsunterschiede bei der topischen Therapie mit dem H-Rezeptor-Antagonisten Azelastin? (OPT-MEDA000063 – OPT-MEDA000068)			
396	03/09/07	Plaintiff's First Amended Rule 26(a)(1) Initial Disclosures (DDX 3 Fishman)			
397	01/14/02	News Release: Medpointe Announces Sales Force Expansion and Agreement with Innovex. (DDX 8 Fishman)			
398	08/20/02	News Release: Medpointe Announces Astelin Co-Promotion Agreement With Sepracor. (DDX 9 Fishman)			
399	09/09/02	News Release: Medpointe Acquires 100% of Astelin Rights in US and Canada. (DDX 10 Fishman)			
400	04/30/04	News Release: Medpointe and Sepracor Agree to Phase out Astelin Co-Promotion. (DDX 11 Fishman)			
401	02/14/06	News Release: Medpointe Launches Astelin Investment Campaign. (DDX 12 Fishman)			
<b>*</b> 402	10/08/03	Patent Security Supplement (MPAT 0000224- MPAT 0000230)			
403	06/14/07	Deposition transcript of R. Duane Sofia			
403A	04/24/07	Letter from S. Benson to LaSalle Process Servers (DDX 27 Sofia)			
403B	12/09/88	Minutes: Wallace/ASTA Developmental Research Satellite Meeting December 8-9, 1988 Cranbury, New Jersey (AS001377- AS001408) (DDX 28 Sofia)			
403C	11/21/83	Memorandum of Record: Minutes of Meeting with Dr. J. Engel, Degussa Pharma (AZ000007- AZ000012) (DDX 29 Sofia)			
403D	06/12/07	Webpage printout for Eisai Co. Ltd (DDX 30)			
403E		Azeptin Information Sheet (DDX 31 Sofia)			
403F	10/09/07	Memorandum from Dr. Gordziel re: Carter-Wallace-Degussa November 1987 Scientific Meeting (AS0001681- AS0001758) (DDX 32 Sofia)			

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EXHIBIT ALSO APPEARS ON PLAINTIFF'S EXHIBIT LIST

403G	06/06/97	Minutes: Wallace/Degussa Joint Scientific Meeting and Toxicology and Pharmaceutical Development Satellite Sessions May 4-6, 1987 Frankfurt, West Germany (AS001832-AS001856) (DDX 33 Sofia)			
403H	06/03/83	Memorandum from D. Sofia to F. Stiefel re: Azelastine Derivatives, Metabolites and Salts (AZ0000552) (DDX 34 Sofia)			
403I	01/16/90	Memorandum from Dr. Gordziel to Dr. Sofia re: ASTA/AWallace Scientific Meeting, April 1990; Proposed Agenda (AS000740- AS000741) (DDX 35 Sofia)			
403J	03/09/90	Telefax from D. Fields to J. Respondek re: enclosure of 02/27/90 draft meeting minutes (AS0001995- AS0002001) (DDX 36 Sofia)			
403K	1970	Excerpts from Remington's Pharmaceutical Sciences. (DDX 37 Sofia)			
404	08/06/06	Expert Report of Eli Meltzer			
405	09/10/07	Opposition Expert Report of Eli Meltzer			
406	08/06/06	Expert Report of Stephen Byrn			
407	09/1/07	Opposition Expert Report of Stephen Byrn			
408	08/06/06	Expert Report of Richard Dalby			
409	09/10/07	Opposition Expert Report of Richard Dalby			
410	07/01/02	News Release: Medpointe Announces Appointment of Experienced Medical/Regulatory Affairs Executive, Richard N. Spivey. (DDX 38 Spivey)			
411		Astelin Product Inset (DDX 40 Spivey)			
412	08/16/04	News release: Astelin (Azelastine Hydrochloride) Nasal Spray Effective in Patients Whose Allergy Symptoms Responded Inadequately to Treatment With Allegra. (DDX 41 Spivey)			
413	05/11/05	News release: Astelin (Azelastine Hydrochloride) Nasal Spray Provided Greater Improvement in Relieving Nasal Allergy Symptoms than Zyrtec. (DDX 42 Spivey)			
414	02/25/07	News Release: Steroid Free Astelin Nasal Spray Demonstrated Seasonal Allergy Symptom Improvement Within 15 Minutes in Clinical Study. (DDX 43 Spivey)			

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EXHIBIT ALSO APPEARS ON PLAINTIFF'S EXHIBIT LIST

415	*			C. LaForce, J. Corren, W. Wheeler, W. Berger, "Efficacy of azelastine nasal spray in seasonal allergic rhinitis patients who remain symptomatic after treatment with fexofenadine," Annals of Allergy, Asthma & Immunology, volume 93, August 2004 (ASC0000130 – ASC0000135)			
416	*	08/00/03		W. Berger, M. White, "Efficacy of azelastine nasal spray in patients with an unsatisfactory response to loratadine Annals of Allergy, Asthma & Immunology, August 2003, Volume 91, Number 2 (ASC0000019 – ASC0000027)			
417	*			J. Corren, W. Storms, J. Bernstein, W. Berger, A. Nayak, H. Sacks, "Effectiveness of Azelastine Nasal Spray Compared with Oral Cetirizine in Patients with Seasonal Allergic Rhinitis, Clinical Therapeutics May 2005 (ASC0000049 – ASC0000049)			
418		09/00/06		W. Berger, F. Hampel, J. Bernstein, S. Shah, H. Sacks, E. Meltzer, "Impact of Azelastine nasal spray on symptoms and quality of life compared with cetirizine oral tablets in patients with seasonal allergic rhinitis," Ann Allergy Asthma Immunol. 2006, 97: 375-381. DDX 48 Spivey			
419		05/30/07		Apotex's Amended Notice of Deposition of Medpointe Healthcare Inc. Pursuant to Fed R.Civ. 30(b)(6) (DDX 51 Sacks)			
420		06/29/07		Plaintiff's Objections & supplemental Response to Apotex's Interrogatory No. 14 (DX 52 Sacks)			
421				Documents cited in Plaintiff's Objections & Supplemental Responses to Apotex's Interrogatory No. 14 Volume 1 (DDX 53 A French)			
422				Documents cited in Plaintiff's Objections & Supplemental Responses to Apotex's Interrogatory No. 14 Volume 2 (DDX 53 B French)			
423		12/22/04		Medpointe Record Retention Policy (AS00000642 – AS00000665) (DDX 54 French)			
424				Document re: location of Carter-Wallace files (DDX 55 French)			
425				Binder containing documents reviewed by Hostler (DDX 57 Hostler)			

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EXHIBIT ALSO APPEARS ON PLAINTIFF'S EXHIBIT LIST



426	07/20/07	Press Release: Meda Enters the US Market through the strategic acquisition of Medpointe Inc (DDX 61 Hostler)		
427	00/00/87	PDR 41 <sup>st</sup> Edition 1987, Product information index (DDX 66 Byrn)		
428	00/00/07	Medco documents re: Migraine Agents (DDX 67 Byrn)		
429		Copy of Astelin Box (Meltzer 6)		
430	10/00/79	Important Advances in Clinical Medicine; Epitomes of Progress – Allergy; The Western Journal of Medicine (Meltzer 9)		
431	00/00/83	Excerpt from Allergy Volume two Principles and Practice (Meltzer 16)		
432	11/24/04	Certified File Wrapper for 60/630,274 (MP2501 – MP2536)		
433	08/06/07	Expert report of Dr. Robert Langer		
433A		Langer Tab 1: Curriculum Vitae of Robert Samuel Langer		
433B		Langer Tab 2: Article form Journal of Pharmaceutical Sciences		
433C		Langer Tab 3: Astelin product insert		
433D		Langer Tab 4		
434	10/15/07	Supplemental Report of Dr. Robert Langer		
434A		Langer Tab A: United States Patent: 4,602,909		
434B		Langer Tab B: Plaintiff's Objections and Supplemental Response to Apotex's Interrogatory No. 14		
434C		Langer Tab C: Article from American Family Physician		
434D		Langer Tab D: Medco document		
434E		Langer Tab E: Langer Laboratory Document		
434F		Langer Tab F: MPAT0000277		
434G		Langer Tab G: MPAT0000404		
434H		Langer Tab H: Asta Pharma Document (AS-MEDA0003522 – AS-MEDA0003525)		
434I		Langer Tab I: MPAT0000187		
435		Second Supplemental Report of Dr. Robert Langer		
436	08/06/07	Expert Report of Maureen D. Donovan		
437		Supplemental Expert Report of Maureen Donovan		
438		German Patent Application 35 39 873 (priority document for '047 patent) (A05397-A05452) (A05457 – A05505)		

439	11/21/1983	Memorandum re Meeting with Dr. J. Engel (AZ00000007 – AZ0000012)			
440	12/04/1984	Handwritten Notes re Degussa Meeting (AZ00000017 – AZ00000031)			
* 441	12/20/1984	Memorandum re Meeting with Chemiewerk Homburg and Organon (AZ00000102 – AZ00000109)			
442					
	08/25/1987	Letter to Dr. Sophia re Azelastine Hydrochloride (AZ00000175 – AZ00000176)			
443		Asta Medica Report re Azelastine Eye Drops (AZ00000186 – AZ00000192)			
444		Report re Azelastine Cream (AZ00000193 – AZ00000195)			
445		Report and Test Results re Azelastine (AZ00000200 – AZ00000224)			
446	08/10/1989	Letter re Draft Agenda for September 1989 Wallace/ASTA Joint Scientific Meeting (AZ00000225 – AZ00000229)			
447	12/8/1988	Agenda for Wallace/ASTA Joint Developmental Research Meeting (AZ00000233 – AZ00000237)			
448	02/00/1983	Report re Physiochemical Properties of Azelastine Hydrochloride (AZ00000240 – AZ00000266)			
449	04/08/1987	Letter to Dr. S. Gordziel re Samples and Documents (AZ00000267 – AZ00000268)			
450		Handwritten Notes re Azelastine Development (AZ00000269 – AZ00000270)			
451	08/00/1991	Asta Medica Report re Azelastine Cream (AZ00000306 – AZ00000340)			
452	03/16/1987	Letter to Dr. Gordziel (AZ00000368)			
453	05/12/1986	Letter to Dr. Gordziel re Azelastine Samples (AZ00000369 – AZ00000373)			
454	08/24/1985	Report re Azelastine Formulations (AZ00000375 – AZ00000379)			
455	11/08/1983	Letter re Questions About Azelastine HCL Dosage Forms (AZ00000380)			
456	11/9/1983	Letter in Response to Questions About Azelastine HCL Dosage Forms (AZ00000381 – AZ00000390)			

457	09/28/1983	Letter to Dr. Gehringer re Several Drugs Including Azelastine (AZ0000409 – AZ0000411)		
458	07/25/1988	Minutes re Azelastine Project Team Meeting No. 57 (AZ0000417 – AZ0000422)		
459	07/23/1987	Memorandum re Azelastine (AZ0000497 – AZ0000500)		
460	09/24/1986	Memorandum re Azelastine Taste Mask Trials (AZ0000501 – AZ0000502)		
461	01/11/1984	Memorandum re Azelastine Requirements (AZ0000537 – AZ0000538)		
462	01/27/58	German Patent: 1178975 (OPT-MEDA000121 – OPT-MEDA000126)		
463	06/30/1988	Various Documents re Azelastine Composition (AZ0000574 – AZ0000583)		
464	06/05/1990	Memorandum re Azelastine Ophthalmic and Topical Formula (AZ0000794 – AZ0000797)		
465	01/05/1922	Physiological Tests of Nose Drops by C. Gallay (Pharmaceutica Acta Helveticae 35, 358-374 (1960) (AZ0000799 – AZ0000819)		
466		Typewritten Notes re Conversation on 6/19/1900 with Dr. Hettche re Azelastine Nasal Spray, Eye Drop and Cream (AZ0000824)		
467	09/00/1989	Asta Pharma Report re Topical Formulations of Azelastine For Tests in Animals (AZ0001031- AZ0001033)		
468	11/01/1991	Memorandum re Azelastine Suspension (AZ0001212 – AZ0001213)		
469	06/08/1992	Memorandum re Astelin Nasal Spray (AZ0001218 – AZ0001219)		
470	06/30/1989	Memorandum re Azelastine Project (AZ0001414 – AZ0001431)		
471	04/24/1989	Memorandum re Azelastine Project (AZ0001492 – AZ0001511)		
472	09/00/1989	Asta Pharma Report re Different Salts of Azelastine: Solubility and Partition Coefficients (AZ0001642 – AZ0001645)		
473		Report re Azelastine (AZ0001649 – AZ0001667)		

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474	01/26/1990	Asta Pharma Report re Azelastine Eye Drops (AZ0001668 – AZ0001684)			
475	05/25/1990	Memorandum re Azelastine HCL (AZ0001685 – AZ0001693)			
476	02/09/1990	Asta Pharma Report re Study on Sensitizing Capacity of IC-5505 (AZ0001704 – AZ0001737)			
477	09/11/1990	Asta Pharma Report re Protective Effect of Azelastine (AZ0001742 – AZ0001746)			
478	03/29/1990	Asta Pharma Report re Azelastine HCL Solution (AZ0001756 – AZ0001818)			
479	11/02/1989	Memorandum re Azelastine HCL (AZ0001874 – AZ0001886)			
*		Report re Influence of Azelastine, Its Metabolites and Analogs on Aeroallergen-Induced Pulmonary Mechanics Changes in Guinea Pig Asthma Model (AZ0002216 – AZ0002223)			
480	05/17/1985	Report re Inhibition of Leukotriene C4 Synthesis By Azelastine and Its Putative Metabolites In Rat Mixed Peritoneal Cells (AZ0002313 – AZ0002327)			
481	12/16/1985	Report re Inhibition of Allergic Histamine Release From Rat Peritoneal Mast Cells By Azelastine (AZ0002340 – AZ0002357)			
482	01/13/1986	Report re Inhibition of Acute Lung Anaphylactic Responses by Azelastine HCL (AZ0002373 – AZ0002387)			
*	484	Report re Influence of Isomers, Metabolites and Analogs of Azelastine on Antigen-Induced Contractile Responses in Rat Trachea (AZ0002388 – AZ0002422)			
*	485	Report re Antagonism of Histamine by Azelastine (AZ0002423 – AZ0002440)			
486	09/03/1986	Report re Effect of Azelastine on Allergic Pulmonary Mechanic Changes in Sensitized Guinea Pigs (AZ0002535 – AZ0002556)			
487	09/04/1986	Report re Effect of Azelastine on 5-HETE Formation in Rat Mixed Peritoneal Cells (AZ0002557 – AZ0002574)			

488	*	11/19/1986	Report re Effect of Azelastine on IgE-Mediated Passive Cutaneous Anaphylaxis in Rats (AZ0002575 – AZ0002585)			
489		11/25/1986	Report re Effect of Azelastine on Phospholipase A2-Induced Airway Hyperactivity in Rat Isolated Tracheal Segments (AZ0002586 – AZ0002613)			
490		12/18/1986	Report re Effect of Azelastine on Calcium Ionophore A23187-Stimulated Leukotriene B4 Synthesis in Rat Mixed Peritoneal Cells (AZ0002614 – AZ0002635)			
491		12/19/1986	Report re Inhibition of Leukotriene C4 Synthesis by Azelastine (AZ0002636 – AZ0002665)			
492		02/02/1987	Report re Effect of Azelastine and Analogs on Carrageenan- and PAF-Induced Rat Paw Edema (AZ0002666 – AZ0002673)			
493		04/13/1987	Report re Effect of Newer Metabolites of Azelastine on Antigen-Induced Responses to Cold Provocation (AZ0002718 – AZ0002731)			
494		06/18/1987	Report re Effect of Azelastine on Allergic LTC4 Synthesis in Guinea Pig Chopped Lung (AZ0002732 – AZ0002753)			
495		06/15/1988	Report re Inhibition of Leukotriene B4 Formation by Azelastine (AZ0002782 – AZ0002802)			
496		07/15/1988	Report re Comparison of the Inhibitory Activity of Azelastine and Analogs (AZ0002858 – AZ0002871)			
497		09/13/1988	Report re Evaluation of Antiasthmatic Activity of Azelastine (AZ0002912 – AZ0002925)			
498		09/21/1988	Report re Inhibition of Leukotriene C4 Formation by Azelastine (AZ0002926 – AZ0002943)			
499		12/05/1988	Report re Effect of Newer Metabolites of Azelastine on Allergic Histamine Secretion (AZ0002956 – AZ0002968)			
500	*	01/03/1989	Report re Effect of Newer Analogs of Azelastine on Allergic Histamine Secretion (AZ0002969 – AZ0002984)			
501		01/03/1989	Report re Antagonism of Ca2+-Induced Contractile Responses by Azelastine (AZ0002985 – AZ0002997)			
502		01/10/1989	Report re Effect of Azelastine on 5-HETE Formation in Rat Mixed Peritoneal Cells (AZ0002998 – AZ0003014)			



503	01/16/1989	Report re Effect of Azelastine on the Gastrointestinal Mucosa In Rats (AZ0003015 – AZ0003024)			
503	01/17/1989	Report re Effect of Azelastine on Allergic Responses to Cold in Rat Tracheal In Vitro (AZ0003025 – AZ0003033)			
505	01/27/1989	Report re Effect of Azelastine on Phospholipase A2-Induced Contractile Responses to Cold in Rat Tracheal Segments (AZ0003034 – AZ0003041)			
506	01/30/1989	Report re Effect of Azelastine Analogs on Antigen and Histamine-Induced Cutaneous Responses in Rats (AZ0003042 – AZ0003052)			
507	01/31/1989	Report re Effect of Azelastine on the Intestinal Mobility in Rats (AZ0003053 – AZ0003059)			
508	05/22/1989	Report re Effect of Azelastine on Tetraethylammonium Induced Airway Hyperactivity to Cooling in Rat Trachea (AZ0003074 – AZ0003088)			
509	05/22/1989	Report re Effect of Azelastine on Calcium Ionophore A23187 Stimulated LTB4 Generation (AZ0003089 – AZ0003104)			
510	05/23/1989	Report re Effect of Azelastine on 5-HETE Formation on Calcium Ionophore A23187 Stimulated 5-HETE Formation (AZ0003105 – AZ0003120)			
511	09/18/1989	Report re Effect of Piperidine and Phenylethyl Analogs on Allergic Histamine Secretion (AZ0003141 – AZ0003153)			
512	11/16/1989	Report re Effect of Azelastine on Tracheal Secretion of Phenol Red in Mice (AZ0003200 – AZ0003206)			
513	01/30/1990	Report re Effect of Azelastine on Tracheobronchial Secretion of Fluorescein Sodium (AZ0003242 – AZ0003250)			
514	05/01/1990	Report re Effect of Newer Backup Compounds of Azelastine of Calcium Ionophore-Stimulated 5-HETE Formation (AZ0003314 – AZ0003326)			
515	06/06/1990	Report re Effect of Analogs on Early Asthmatic Responses (AZ0003327 – AZ0003340)			
516	06/13/1990	Report re Effect of Azelastine Backups on Allergic Histamine Secretion (AZ0003341 – AZ0003354)			

517	08/13/1990	Report re Effect of Azelastine Backup Compounds on Allergic Responses to Cold Provocation (AZ0003355 – AZ0003362)			
518	11/12/1990	Report re Effect of Azelastine Backup Compounds on Early Asthmatic Responses (AZ0003397 – AZ0003405)			
519	03/21/1991	Report re Effects on Calcium Ionophore-Stimulated LTC4 Formation (AZ0003406 – AZ0003421)			
520	03/21/1991	Report re Effects on Calcium Ionophore-Stimulated LTC4 Formation (AZ0003422 – AZ0003437)			
521	07/09/1991	Report re Effect of Azelastine on Aeroallergen-Induced Bronchial Eosinophilia (AZ0003468 – AZ0003485)			
522	12/04/1986	Report re Ability of Azelastine to Inhibit Formation of Calcium Ionophore A23187 Stimulated Leukotriene B4 (AZ0003948 – AZ0003968)			
523	12/19/1986	Report re Inhibition of Leukotriene C4 Synthesis By Azelastine (AZ0003969 – AZ0003998)			
524	04/13/1987	Report re Effect of Azelastine Metabolites on Antigen-Induced Responses to Cold Provocation (AZ0003999 – AZ0004012)			
525	05/22/1989	Report re Effect of Azelastine on Calcium Ionophore A23187 LTb4 Generation (AZ0004013 – AZ0004015)			
526	05/23/1989	Report re Effect of Azelastine on 5-HETE Formation on Calcium Ionophore A23187 Stimulated 5-HETE Formation (AZ0004016 – AZ0004031)			
527	04/11/1987	Degussa Report re Comparison of the Effects of Azelastine Following Intravenous Administration of the Ovalbumin-Induced Bronchospasm (AZ0004034 – AZ0004045)			
528	06/25/1987	Letter to Dr. Sophia re Inhibitory Potency of Azelastine on H1 Receptors (AZ0004058 – AZ0004059)			
529	03/01/1985	Report re Pharmacological Summary of Azelastine (AZ0004131 – AZ0004190)			
530	04/03/1992	Report re Azelastine on Aeroallergen-Induced Bronchial Eosinophilia in Guinea Pigs (AZ0004204 – AZ0004227)			

531	02/27/1984	Report re Inhibition of Allergic and Nonallergic Histamine Secretion by Azelastine in Rat Peritoneal Mast Cells (AZ0004717 – AZ0004736)			
532	08/11/1992	Memorandum re Asta Study No. 888186 (AZ0005166 – AZ0005165)			
533	10/19/1992	Memorandum re Azelastine Asta Report: Investigation on the Toxicokinetic Profile of Azelastine (AZ0006423 – AZ0006584)			
534		Report re Pharmacokinetics of Azelastine and Metabolite in Guinea Pigs (AZ0006905 – AZ0006908)			
535	06/07/1988	Letter to Dr. Sophia re Dr. Diamantis' Presentations (AZ0006930 – AZ0006947)			
536	05/12/1988	Letter to Dr. Herbst re Experimental Results re Azelastine (AZ0007084 – AZ0007103)			
537	08/04/1989	Letter to Dr. Fricke re Inventory and Assay Results from Dog Plasma Samples (AZ0007728 – AZ0007730)			
538	03/21/1989	Letter to Dr. Fricke re Assay and Analysis Results of Dog Plasma Samples (AZ0007751 – AZ0007752)			
539	06/05/1987	Handwritten notes and Agenda from Meeting re Azelastine Modes of Action and Implications (AZ0007792 – AZ0007828)			
540		Azelastine and Desmethyazastine Suppress Acetylcholine-Induced Contraction and Depolarization in Human Airway Smooth Muscle (AZ0007868 – AZ0007879)			
541	10/29/1990	Report re Azelastine and Desmethyazastine Suppress Acetylcholine-Induced Contraction and Depolarization in Human Airway Smooth Muscle (AZ0007988 – AZ0008001)			
542	06/27/1991	Report re Effect of Azelastine Backup Compounds on Leukotriene B4 Formation (AZ0008294 – AZ0008312)			
543	04/15/1988	Lab Notebook (AZ0008565 – AZ0008622)			
544	05/08/1985	Lab Notebook (AZ0008649 – AZ0008788)			
545	09/29/1985	Lab Notebook (AZ0008894 – AZ0009068)			
546	09/25/1986	Lab Notebook (AZ0009069 – AZ0009239)			
547	09/21/1987	Lab Notebook (AZ0009240 – AZ0009383)			

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548	02/02/1989	Lab Notebook (AZ0009384 – AZ0009492)		
549	08/04/1989	Lab Notebook (AZ0009493 – AZ0009602)		
550	09/25/1986	Lab Notebook (AZ0009758 – AZ0009813)		
551	01/13/1986	Lab Notebook (AZ0009918 – AZ0009940)		
552	07/28/1989	Lab Notebook (AZ0010224 – AZ0010270)		
553	02/11/1988	Lab Notebook (AZ0010383 – AZ0010469)		
554	02/11/1988	Lab Notebook (AZ0010470 – AZ0010567)		
555	03/29/1988	Lab Notebook (AZ0011236 – AZ0011275)		
556	12/06/1984	Lab Notebook (AZ0011509 – AZ0011728)		
557	07/30/1992	Lab Notebook (AZ0011778 – AZ0011914)		
558	02/02/1989	Lab Notebook (AZ0011915 – AZ0011993)		
559	10/16/1986	Lab Notebook (AZ0011994 – AZ0012100)		
560	08/04/1989	Lab Notebook (AZ0012305 – AZ0012489)		
561	07/30/1992	Lab Notebook (AZ0012702 – AZ0012744)		
562		Lab Notebook (AZ0012745 – AZ0012811)		
563	07/02/1992	Lab Notebook (AZ0012812 – AZ0012856)		
564	08/19/1991	Lab Notebook (AZ0012857 – AZ0012897)		
565	10/27/1986	Memorandum re Meeting with Degussa Pharma Representatives (AZ0013916 – AZ0013978)		
566		Test Results (AZ0014000)		
567		Test Results re Azelastine Study No. 83H221 (AZ0014379 – AZ0014400)		
568	04/28/1989	Report re Pharmacokinetics of Azelastine in Guinea Pig (AZ0015675 - AZ0015764)		
569	04/28/1989	Addendums #1 and #2 to Report re Pharmacokinetics of Azelastine in Guinea Pig (AZ0015765 – AZ0015768)		
570	09/28/1989	Report re C-Metabolic Profiles in Selected Tissues After A Does of Azelastine (AZ15877 – AZ0015906)		
571	10/20/1989	Report re Disposition of Azelastine in Male Guinea Pigs (AZ0015907 – AZ0015927)		
572	09/28/1989	Report re Pharmacokinetics of Azelastine (AZ0015928 – AZ0015994)		
573	11/16/1989	Report re Effect of Azelastine on Tracheal Secretion in Mice (AZ0016703 – AZ0016709)		

574	04/22/1991	Report re Effect of Azelastine Pamote Salt on Antigen-, Histamine- and 5-HT- Induced Cutaneous Responses in Rats (AZ0016710 – AZ0016719)			
575	10/01/1990	Report re Effect of Azelastine Backups on TEA-Induced Airway Hyper-responsiveness (AZ0016720 – AZ0016733)			
576	02/12/1990	Report re Effect of Azelastine Backups on Calcium Ionophore Secretion (AZ0016734 – AZ0016745)			
577	02/26/1990	Report re Effect of Azelastine on Tetraethylammonium-Induced Airway Hyper-reactivity (AZ0016746 – AZ0016759)			
578	11/16/1989	Report re Effect of Azelastine on Tracheal Secretion of Phenol Red in Mice (AZ0016760 – AZ0016766)			
579	11/27/1989	Report re Summary of the Pharmacologic Activity of W-3006M (AZ0016767 – AZ0016791)			
580	04/21/1989	Report re Three Month Oral Toxicity Study of Azelastine (AZ16812 – AZ0016937)			
581	10/17/1989	Report re Determination of Azelastine in Rabbit Plasma (AZ0017109 – AZ0017139)			
582	09/06/1988	Report re Segment II Study of an Azelastine Stimulated Release in Rabbits (AZ0017143 – AZ0017226)			
583	08/26/1988	Report re Determination of Azelastine in Rabbit Plasma (AZ0017231 – AZ0017277)			
584		Test Results re Azelastine (AZ0017387 – AZ0017463)			
585	02/19/1992	Report re Plasma Levels of Azelastine In Mice (AZ0018315 – AZ0018320)			
586	02/26/1992	Letter to Dr. Sophia and Protocol Drafts of Azelastine Toxicity Study (AZ0018340 – AZ0018364)			
587		Draft Study Protocol: Investigation on the Pharmacokinetics of Azelastine in the Mouse (AZ0018368 – AZ0018381)			
588	06/23/1989	Report re Six-Month Intranasal Toxicity Study (AZ0018424 – AZ0018434)			
589	12/21/1981	Azelastine Testing Conception (AZ0018959 – AZ0018984)			

590	01/18/1982	Letter to Dr. Perhach and Synopsis of Pharmacological, Toxicological and Clinical Findings with Azelastine (AZ0019008 – AZ0019042)		
591	11/02/1983	Allergic Properties of Azelastine Hydrochloride and its Main Metabolite 6-Hydroazelastine Studies In Vitro by Y. Sakuma (Ibaragi 300-26, Japan) (AZ19113 – AZ0019115)		
592	05/18/1983	Studies on the Metabolism of 14 C-A-5610 x HCL in Rats (AZ0019162 – AZ0019183)		
593		Physical Sample: CromoHEXAL Nasenspray		
593A		Product Insert for: CromoHEXAL Nasenspray		
594		Physical Sample: Ratiopharm Heuschnupfen-spray		
594A		Product Insert for: Ratiopharm Heuschnupfen-spray		
595		Physical Sample: Livocab Nasenspray		
595A		Product Insert for: Livocab Nasenspray		
596		Physical Sample: Livocab (Beclometason 0.05%) Nasenspray		
596A		Product Insert for: Livocab (Beclometason 0.05%) Nasenspray		
597		Physical Sample: Bausch & Lomb Vividrin akut Nasenspray		
597A		Product Insert for: Bausch & Lomb Vividrin akut Nasenspray		
598		Physical Sample: Bausch & Lomb Vividrin Nasenspray		
598A		Product Insert for: Bausch & Lomb Vividrin Nasenspray		
599	11/19/63	German Patent: 1208036 (OPT-MEDA000127 – OPT-MEDA000128)		
600		Product Insert for Vividrin (OPT-MEDA000280)		
601	02/17/95	Meeting minute notes with handwritten notes (OPT-MEDA000467)		
602	09/06/85	Memo from Dr. Aurich to Dr. Breuel re: Azelastin-Nasenspray (OPT-MEDA000557 – OPT-MEDA558)		
603	06/16/87	Summary Report of Clinical Trial (OPT-MEDA000579 – OPT-MEDA000583)		

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604	03/05/87	Summary Report of Clinical Trial (OPT-MEDA000584 – OPT-MEDA000588)			
605	02/20/87	Summary Report of Clinical Trial (OPT-MEDA000589 – OPT-MEDA000596)			
606		German Article (OPT-MEDA0006000 – OPT-MEDA000615)			
607	05/31/88	Memo from Dr. Herbst to Dr. Hettche (OPT-MEDA001268)			
608	05/25/88	Memo from Dr. Hettche to Dr. Engel (OPT-MEDA001269)			
609	10/28/89	Asta Pharma Report: Report on Anti-allergic Formulations Administered By Conjunctival Topical Route (OPTI0000199 – OPTI0000213)			
610	06/15/88	Asta Pharma Report: Ocular antihistmanic activity in rabbit (OPTI0000218 – OPTI0000232)			
611	06/15/88	Asta Pharma Report: Comparative ocular antihistaminic activity (OPTI0000241 – OPTI0000253)			
612	02/09/90	Asta Pharma Report: Study on the sensitizing capacity of LC-5505 by ocular application (OPTI0000262 – OPTI0000296)			
613	04/25/88	Asta Pharma Report: Examination of the Surface Anaesthetic Action of Azelastine-HCL on the Cornea of the Albino Rabbit (OPTI0000301 – OPTI0000314)			
614	04/21/88	Asta Pharma Report: LC-5505: Determination of its anaesthetic activity. Comparison with benoxinate and atazoline (OPTI0000316 – OPTI0000329)			
615	04/21/88	Asta Pharma Report: LC55-05: Determination of its anaesthetic activity. Comparison with benoxinate and atazoline (OPTI0000348 – OPTI0000361)			

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616			Asta Pharma Report: Study of the effect of LC-5505 at 0.1% on the corneal reepithelialization process in rabbits (OPTI0000367 – OPTI0000378)			
617	01/22/81		Degussa Report: The Study of Azelastine in Aqueous Solution for Irritating Effects on the Mucous Membrane Following Single Application to the Eye of the Rabbit (OPTI0000597 – OPTI0000613)			
618	02/24/86		Degussa Report: Azelastine 0.2% Nasal Spray. Testing the mucous membrane irritancy after repeated application to the rabbit eye for 5 days (OPTI0000615 – OPTI0000650)			
619	05/06/87		Degussa Report: Testing the mucous membrane irritancy after repeated application to the rabbit eye for 5 days (OPTI0000652 – OPTI0000698)			
620	02/26/86		Asta Pharma Report: Compared acute ocular tolerance (OPTI0001165 – OPTI0001173)			
621	02/11/87		Asta Pharma Report: Compared acute ocular tolerance (OPTI0001179 - OPTI0001188)			
622	04/25/88		Asta Pharma Report: Examination of the Surface Anaesthetic Action of Azelastine-HCL on the Cornea of the Albino Rabbit (OPTI0001265 – OPTI0001278)			
623	01/23/99		Azelastine Eye Drops. IND #54,893 Asta Medica, Inc. Annual Progress Report (OPTI0002147 – OPTI0002182)			
624	05/12/00		Asta Pharma Report: Clinical trial to assess efficacy and safety of azelastine eye drops in patients with perennial allergic conjunctivitis/rhinoconjunctivitis (OPTI0002598 – OPTI0002927)			
625			Azelastine Eye Drops-Pre IND Meeting: Introduction and Rationale for US Clinical Program Summary of European Clinical Studies (OPTI0004107 – OPTI0004112)			

626	1988	A. Abbah and M. Marzetto; "Azelaistine Eye Drops in the Treatment of Seasonal Allergic Conjunctivitis or Rhinconjunctivitis in Young Children", reprinted from Current Medical Research and Opinion Vol. 14 No. 5 1988 (OPTN0000422 – OPTN0000431)			
627		Zaditor Product Monograph (OPTN0000458 – OPTN0000473)			
628	09/08/00	Letter from W. Rumble to I. Army re: response to Ast Medica's 08/25/00 submission (OPTN0001644 – OPTN0001647)			
629		Optivar product insert (OPTN0001714 – OPTN0001715)			
630		Application Summary (OPTN0002073 – OPTN0002241)			
631		Official Hague Convention Documents relating to the testimony of Dr. Jurgen Engel, Including Letters of Requests and Official Transcripts from the German Court (including exhibits)			
631A		Request for Judicial Assistance with German Translation			
631B		Questionnaire for Dr. Jurgen Engel with German translation			
631C		List of exhibits for Dr. Jurgen Engel with German translation			
631D		United States Patent: 5,164,194 with German translation (Engel 1)			
631E		United States Patent: 4,704,387 with German translation (Engel 2)			
631F	03/27/86	German Patent: DE 3530793 AI (MPAT0246 – MPAT0272) (Engel 3)			
631G		Engel 4			
631H	09/30/85	Memo from Dr. Hettche to Dr. Aurich re: Azelastin-Nasenspray (AS-MEDA0009924) (Engel 5)			
631I	07/27/72	German Patent: 2164058 (MPAT0209 – MPAT0245) (Engel 6)			
631J	02/16/87	Tuckerman Declaration with translation (Engel 7)			

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631K	01/23/90	Szelenyi Declaration with translation (MP0063 – MP0064) (MP0062) (Engel 8)			
631L		Article from Aerosols in Medicine (Engel 9)			
631M		VADE-MECUM for Pharmacist 12 <sup>th</sup> revised edition (AS-MEA0000624- AS-MEDA0000629) (Engel 10)			
631N	09/13/88	ASTA Pharma report: Development pharmaceuticals of Azelastine Hydrochloride 0.1% Nasal Spray with translation (AS- MEDA0003522-AS- MEDA0003525) (Engel 11)			
631O	05/30/07	Deposition of Jurgen Engel with translation			
632		Number not used			
633		Official Hague Convention Documents relating to the testimony of I. Szelenyi, Including Letters of Requests and Official Transcripts from the German Court (including exhibits			
633A		Request for Judicial Assistance with German Translation			
633B		Questionnaire for Dr. Istvan Szelenyi with German translation			
633C		List of exhibits for Dr. Istvan Szelenyi with German translation			
633D	11/17/92	United States Patent: 5,164,194 with German translation (Szelenyi 1)			
633E	01/23/90	Szelenyi Declaration (MP0063 – MP0064) (Szelenyi 2)			
633F	11/03/87	United States Patent: 4,704,387 with German translation (Szelenyi 3)			
633G	06/01/90	Szelenyi Declaration (MP00669 – MP0070) (Szelenyi 4)			
633H	09/20/07	Deposition of Istvan Szelenyi with translation			
634		Official Hague Convention Documents relating to the testimony of H. Hettche, Including Letters of Requests and Official Transcripts from the German Court (including exhibits			
634A	05/30/07	Request For Judicial assistance with German translation			
634B		Questionnaire for Helmut Hettche with German translation			
634C		List of Exhibits Helmut Hettche with German translation			
634D		German Patent Application 268772 (with English translation) (Hettche 1)			

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634E	11/17/92	Unites States Patent: 5,164,194 with German translation (Hettche 2)		
634F	10/27/88	European Patent Application 0 316 633 B1 (Original & English translation) (Hettche 3)		
634G	03/08/96	Decision about the Revocation of the European Patent (Article 101(1) of the EPC) (Original and English translation) (MPAT0000395 – MPAT0000421) (Hettche 4)		
634H	04/05/00	Decision of the Technical Court of Appeals 3.3.2 of April 5, 2000 (Original and English translation) (MPAT0000245 – MPAT0000265) (Hettche 5)		
634I		German Patent 21 64 058 (with English translation) (MP0209 – MP0245) 9Hettche 6)		
634J	05/28/74	United States Patent: 3,813,384 with German translation (Hettche 7)		
634K		N. Brock, D. Lenke H. Abel, "Expose on the Pharmacology and Toxicology of the Antihistamine Preparation ASTA A 5610, " From the Pharmacology Department of Asta-Werke AG, Chemische Fabrik, Brackwede/Westf (AT00001098 – AT00001105) Original & German translation) (Hettche 8)		
634L		Sofia Abstract with German translation (Hettche 9)		
634M		(AS-MEDA0001568) (Hettche 10)		
634N	9/6/85	Degussa document (AS- MEDA0000601- AS-MEDA0000602) (Hettche 11)		
634O	01/27/86	Memo from Dr. Hettche to Dr. Herbsrt re: Azelastin nasal spray (AS-MEDA0004168 – AS-MEDA0004169) (Original and translation) Hettche 12)		
634P	08/13/90	Memo from Dr. Hettche to Dr. Herbst (AS-MEDA0001345) Hettche 13		
634Q	02/18/06	Handwritten Notes (Hettche 14)		
634R	8/12/87	AS-MEDA0000600 (Hettche 15)		
634S	11/03/87	Unites States Patent: 4,704,387 with German translation (Hettche 16)		
634T	09/17/86	German Patent Application 928458, (Original and translation) (A05457 – A05505) (Hettche 17)		
634U	08/22/85	German Patent Application 34 8 776.8 (Hettche 18)		

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634V		VADE-MECUM for Pharmacist 12 <sup>th</sup> revised edition (AS-MEA0000624- AS-MEDA0000629) (Hettche 19)			
634W	00/00/71	H. Breuninger, "Nasentropfen, Ohrentropfen," ["Nasal Drops, ear drops"], HNO, Vol. 19, Issue 3, pp. 65-68 (March 1971)(A06107-A06110) (Hettche 20)			
634X		Scheduling status document (A06012 – A-06015) (Hettche 21)			
634Y	00/00/78	H. Sucker, P. Fuchs, P. Speiser, Pharmazeutische Technologie (AS-MEDA0007754 – AS-MEDA0007755) (Original & translation) (Hettche 22)			
634Z	00/00/81	H.J.M. van de Donk, J. Zuidema and F.W.H.M. Merkus, "The effects of nasal drops on the ciliary beat frequency of chicken embryo tracheas," Rhinology, Vol. 19, pp. 215-230 (1981)(Hettche 23).			
634AA		Article in foreign language entitled, "Allergie gegen topische Antihistaminika - Diskrepanz zwischen Literatur und Praxis" (A05987 - A05989) (Hettche 24)			
634BB	09/13/88	ASTA Pharma report: Development pharmaceuticals of Azelastine Hydrochloride 0.1% Nasal Spray (AS-MEDA0003522-AS- MEDA0003525) Hettche 25			
634CC	01/23/90	Szelenyi Declaration with German Translation (MPAT0063 – MPAT0064 (Hettche 26)			
634DD		Excerpt from File History with English translation (MP0062) (Hettche 27)			
634EE	06/01/90	Szelenyi Declaration with German translation (MP0069 – MP0070)(Hettche 28)			
634FF	12/04/07	Deposition transcript of Helmut Hettche with translation			
635	03/24/72	Abstract from Science Vol. 75: Cilia: Activation Coupled to Mechanical Stimulation by Calcium Influx			
636	1983	Application Pharmacology: Pharmacometrics Vol. 26 No. 2			
637	1986	N. Bonini, M. Gustin, D. Nelson; "Regulation of Ciliary Motility by Membrane Potential in Paramecium: A Role for Cyclic AMP, Cell Motility and Cytoskeleton 6:256-272 (1986)			

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638	1985	T. Hennessey, "Injected cyclic AMP increases ciliary beat frequency in conjunction with membrane hyperpolarization, European Journal of Cell Biology 36, 153-156 (1985)			
639	1992	K. Thomas, S. Ollier, H. Ferguson, R. Davies; "The effect of intranasal azelastine, Rhinolast, on nasal airways obstructions and sneezing following provocation testing with histamine and allergen; Clinical Experimental Allergy, 1992 Volume 22 pages 642-647			

# **EXHIBIT 16**

## EXHIBIT 16

**PLAINTIFF'S OBJECTIONS TO DEFENDANTS' LIST OF TRIAL EXHIBITS**

Attached are Plaintiff's objections to Defendants' list of trial exhibits, except as to the accuracy of translations.

Plaintiff reserves the right to make additional objections to any exhibit, including objections as to foundation, depending on the witness through which Defendants seek to introduce the exhibit.

The following abbreviations are used for Plaintiff's objections to Defendants' list of trial exhibits:

<b>106</b>	FRE 106 (Incomplete)
<b>402</b>	FRE 402 (Relevance)
<b>1006</b>	FRE 1006 (Improper summary of voluminous records)
<b>F</b>	Foundation (includes FRE 901)
<b>H</b>	Hearsay (includes FRE 802)
<b>X</b>	Not produced in this action
<b>32</b>	Fed. R. Civ. P. 32

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

MEDPOINTE HEALTHCARE INC., )  
 )  
 Plaintiff/Counter-Defendant, ) C.A. No. 06-164 (SLR)  
 )  
 v. )  
 )  
 APOTEX INC. and APOTEX CORP., )  
 )  
 Defendants/Counter-Plaintiffs. )

**DEFENDANTS TRIAL EXHIBIT LIST**

TRIAL EXHIBIT NUMBER	DATE	DESCRIPTION	WITNESS	ADMIT	OBJECTION
<b>*</b> 1	03/00/50	S.M. Feinberg, "Drugs In Allergy," Trans. Amer. Acad. Of O&O, Vol. 124 (March-April 1950), pp. 283-286 (A00085 – A00088). Meltzer 11			402, F, H
<b>*</b> 2	05/00/50	E.L. Keeney, "Medical Progress: Histamine and the Antihistaminic Drugs," California Medicine, Vol. 72, No. 5, pp. 377-389 (May 1950)(A00089–A00104).			402, F, H
3	00/00/69	R. Barkman, M. Germanis, G. Karpe and A.S. Malmborg, "Preservatives In Eye Drops," Acta Ophthalmologica, Vol 47, No. 1, pp. 461-475 (1969)(A00105 – A00120).			402, F, H
<b>*</b> 4	00/00/70	A.J. Bentley and R.T. Jackson, "Changes in the Patency of the Upper Nasal Passage Induced by Histamine and Antihistamines," The Laryngoscope, Vol. 80, No. 12, pp. 1859-1870 (1970)(A00121–A00132).			402, F, H
<b>*</b> 5	11/00/74	J.A. Blue, "Current Concepts of Allergy of the Eye," Annals of Allergy, Vol. 33, pp. 267-273 (November 1974)(A00139–A00146).			402, F, H

**\*** EXHIBIT ALSO APPEARS ON PLAINTIFF'S EXHIBIT LIST

<b>*</b> 6	04/15/75	U.S. Patent No. 3,878,217 issued April 15, 1975 (A00147 – A00156).			402
<b>*</b> 7	00/00/76	D.S. Pearlman, "Antihistamines: Pharmacology and Clinical Use," Drugs, Vol. 12, No. 1, pp. 258 – 273 (1976)(A00157–A00174).			402, F, H
<b>*</b> 8	00/00/76	A.A. Kassem, E. Nour El-Din, N.M. Mursi, A. Abd Elbary and N. Foda, "Formulation and Stabilization of Antazoline Hydrochloride Nasal Drops," Bulletin of the Faculty of Pharmacy, Vol. 15, No. 2, pp. 161-175 (1976)(A00175 – A00193).			402, F, H
<b>*</b> 9	00/00/76	H.C. Ansel, "Chapter 11 – Ophthalmic Preparations" and "Chapter 12 – Ear, Nose, and Topical Preparations," Introduction to Pharmaceutical Dosage Forms, 2nd Ed., pp. 333-349, (Lea & Febiger – Philadelphia)(1976)(A00194 – A00212).			402, F, H
<b>*</b> 10	08/00/78	L.H. Hamilton, "Effect of Topical Decongestants on Nasal Airway Resistance," Current Therapeutic Research, Vol. 24, No. 3, pp. 261-268 (August 1978)(A00213 – A00221).			402, F, H
<b>*</b> 11	00/00/79	K. Tasaka and M. Akagi, "Anti-allergic Properties of a New Histamine Antagonist, 4-(p-Chlorobenzyl)-2-[N-methyl-perhydroazepinyl-(4)]-1-(2H)-phthalazinone Hydrochloride (Azelastine)," Arzneimittelforschung/Drug Research, Vol. 29, No. 3, pp. 488-493 (1979)(A00222 – A00229).			402, F, H
<b>*</b> 12	00/00/79	Physicians Desk Reference, 33rd Edition, pp. 873, 892, 1512 and 1851 (1979)(A00230 – A00235).			402, F, H, 106
<b>*</b> 13	00/00/80	R.R. File and T.F. Patton, "Topically Applied Pilocarpine," Archives of Ophthalmology, Vol. 98, No. 1, pp. 112-115 (January 1980)(A00236-A00241).			402, F, H
<b>*</b> 14	00/00/80	K. Tatsumi, T. Ou, H. Yamada and H. Yoshimura, "Studies on Metabolic Fate of a New Antiallergic Agent, Azelastine (4-(p-Chlorobenzyl)-2-[N-Methylperhydroazepinyl-(4)]-1-(2H)-Phthalazinone Hydrochloride)," Japan J. Pharmacol. Vol. 30, pp. 37-48 (1980)(A00242–A00253).			402, F, H

15	*	00/00/80	Physicians' Desk Reference for Nonprescription Drugs, First Edition, pp. 502-03, 506, 522, 539, 553, 616, 637-38, 646, 654-55 (1980)(A00276 – A00289).			402, F, H, 106
16	*	00/00/81	W. Diamantis, J.E. Harrison, J. Melton, J.L. Perhach, Jr., and R.D. Sofia, "In Vivo and In Vitro H1 Antagonist Properties of Azelastine," Vol. 23, No. 3, The Pharmacologist (1981), p. 149 (A00290-A00293).			402, F, H
17	*	03/03/81	U.S. Patent No. 4,254,129 issued March 3, 1981 (A00294 – A00304).			402
18	*	09/00/81	S.W. Lam, R.C. Meyer and L.T. Takahashi, "Determination of Thimerosal in Ophthalmic Solutions by Redial Compression Separation HPLC," Journal of Parental Science and Technology, Vol. 35, No. 5, pp. 262-265 (September-October 1981)(A00305 – A00308).			402, F, H
19	*	00/00/82	W. Diamantis, N. Chand, J.E. Harrison, J. Pillar, J.L. Perhach, Jr. and R.D. Sofia, "Inhibition of Release of SRS-A and Its Antagonism by Azelastine (A), An H1 Antagonist-Antiallergic Agent," The Pharmacologist, 24, No. 82, p. 200 (1982)(A00325--A00328).			402, F, H
20	*	02/00/82	U.S. Patent No. 4,313,931 issued February 2, 1982 (A00329 – A00339).			402
21		09/00/82	C. Secher, J. Kirkegaard, P. Borum, A. Maansson, P. Osterhammel and N. Mygind, "Significance of H1 and H2 receptors in the human nose: rationale for topical use of combined antihistamine preparations," The Journal of Allergy and Clinical Immunology, Vol. 70, No. 3, pp. 211-218 (September 1982)(A00340--A00349).			402, F, H
22	*	00/00/82	R.C. Kersten, "Ophthalmic Drugs," Primary Care: Clinics in Office Practice, Vol. 9, No. 4, pp. 743-756 (December 1982)(A00350 – A00365).			402, F, H
23	*	00/00/82	J. Kirkegaard, C. Secher, and N. Mygind, "Effect of the H1 Antihistamine Chlorpheniramine Maleate on Histamine-Induces Symptoms in the Human Conjunctiva," Allergy, Vol. 37, pp. 203-208 (1982)(A00366-A00371).			402, F, H

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24	00/00/82	H.J.M. van de Donk, A.L.M. van Egmond, A.G.M. van den Heuvel, J. Zuidema and F.W.H.M. Merkus, "The effects of drugs on ciliary motility III. Local anaesthetics and anti-allergic drugs," Int'l J. of Pharmaceutics, 12, pp. 77-85 (1982)(MPAT0000523-MPAT0000531)(AS-MEDA0001837-AS-MEDA0001845)(A00372-A00380).			F
* 25	07/00/83	E. Duzman, J. Anderson, J. Vita, J.C. Lue, C. Chen and I. Leopold, "Topically Applied Oxymetazoline – Ocular Vasoconstrictive Activity, Pharmacokinetics, and Metabolism," Archives of Ophthalmology, Vol. 101, pp. 1122-1126 (July 1983)(A00381-A00385).			402, F, H
* 26	00/00/83	J. Kirkegaard, C. Secher, P. Borum, and N. Mygind, "Inhibition of Histamine-Induced Nasal Symptoms by the H1 Antihistamine Chlorpheniramine Maleate: Demonstration of topical effect," Br. J. Dis. Chest 77, pp. 113-122 (1983)(A00386-A00395). Meltzer 10			402, F, H
* 27	01/00/84	R.M. Naciero, H.L. Meier, A. Kagey-Sobotka, P.S. Norman and L.M. Lichtenstein, "In Vivo Model for the Evaluation of Topical Antiallergic Medications," Archives of Otolaryngology, Vol. 110, No. 1, pp. 25-27 (January 1984)(A00396-A00400).			402, F, H
* 28	02/07/84	U.S. Patent No. 4,430,343 issued February 7, 1984 (A00401 – A00413).			402
29	06/00/84	M.J. Reader, "Influence of Isotonic Agents on the Stability of Thimerosal in Ophthalmic Formulations," Journal of Pharmaceutical Sciences, Vol. 73, No. 6, pp. 840-841 (June 1984)(A00414-A00415).			402, F, H
* 30	12/00/84	K. Tatsumi, H. Yamada, H. Yoshimura, Y. Nishizawa, M. Sakai, H. Mizuo and C. Yamato, "Metabolism of an Antiallergic Agent, Azelastine (4-(p-Chlorobenzyl)-2-[N-Methylperhydroazepinyl-(4)]-1-(2H)-Phthalazine Hydrochloride] in Rats and Guinea Pigs," Hiroshima Journal of Medical Sciences, Vol. 33, No. 4, pp. 669-678 (December 1984)(A00416-A00426).			402, F, H

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32	*	00/00/85	N. Chand, J. Pillar, W. Diamantis and R.D. Sofia, "Inhibition of Allergic Histamine Release by Azelastine and Selected Antiallergic Drugs from Rabbit Leukocytes," International Archives of Allergy and Applied Immunology, Vol. 77, No. 4, pp. 451-455 (1985)(A00435-A00441).			402, F, H
33	*	00/00/85	N.L. Burstein, "The Effects of Topical Drugs and Preservatives on the Tears and Corneal Epithelium in Dry Eye," Trans. Ophthalmol. Soc. U.K., Vol. 104, pp. 402-409 (1985)(A00442-A00449).			402, F, H
34	*	00/00/85	J. Fräki, K. Kalimo, P. Tuohimaa and E. Aantaa, "Contact Allergy to Various Components of Topical Preparation for Treatment of External Otitis," Acta Otolaryngol (Stockh), 100, pp. 414-418 (1985)(A00450-A00454).			402, F, H
35	*	01/10/86	A.G. Toggias, R.M. Nacieno, J. Warner, D. Proud, A. Kagey-Sobotka, I. Nimmagadda, P.S. Norman and L.M. Lichenstein, "Demonstration of Inhibition of Mediator Release From Human Mast Cells by Azatadine Base," JAMA, Vol. 255, No. 2, pp. 225-229, (Jan. 10, 1986)(A00455 - A00461).			402, F, H
36	*	06/00/86	H.A. Orgel, E. Meltzer, J. Kemp and M.J. Welch, "Clinical rhinomanometric, and cytologic evaluation of seasonal allergic rhinitis treated with beclomethasone dipropionate as aqueous nasal spray or pressurized aerosol," J. Allergy Clin. Immunol., Vol. 77, No. 6, pp. 858-864 (June 1986)(A00462-A00468).			402, F, H
37	*	00/00/86	G. Vanden Bussche, "Levocabastine Hydrochloride," Drugs of the Future, Vol. 11, No. 10, pp. 841-843 (1986)(A00469-A00471).			402, F, H

38	*	11/00/86	T.E. Havas, P. Cole, L. Parker, D. Oprysk and A. Ayiomamitis, "The effects of combined H1 and H2 histamine antagonists on alterations in nasal airflow resistance induced by topical histamine provocation," J. Allergy Clin. Immunol., vol. 78, No. 5, Part 1, pp. 856-860 (November 1986)(A00472-A00476).			402, F, H
39	*	00/00/86	Y. Saito, "Recent Trends in Aerosol Therapy for Allergic Rhinitis," Z. Erkrank. Atm.org. 166, No. 1, pp. 25-29 (1986)(A00477-A00481).			402, F, H
40	*		A. Pécoud, P. Zuber, and M. Kolly, "Effect of a New Selective H1 Receptor Antagonist (Levocabastine) in a Nasal and Conjunctival Provocation Test," Int. Archs Allergy appl. Immun. 82, pp. 541-543 (1987)(A00482-A00486).			402, F, H
41	*	00/00/87	N. Kubo, O. Shirakawa, T. Kuno, and C. Tanaka, "Antimutagenic Effects of Antihistamines: Quantitative Evaluation by Receptor-Binding Assay," Japan J. Pharmacol. 43, pp. 277-282 (1987)(A00487-A00492).			402, F, H
42	*	04/00/87	J.M. Lancer, A.S. Jones, J.C. Stevens and E. Beekingham, "A comparison by rhinomanometry of beclomethasone and terfenadine in the treatment of seasonal rhinitis," The Journal of Laryngology and Otology, Vol. 101, pp. 350-354 (April 1987)(A00493-A00497).			402, F, H
43	*	04/00/87	E. O. Meltzer and M. Schatz, "Pharmacotherapy of Rhinitis - 1987 and Beyond," Immunology and Allergy Clinics of North America, Vol. 7, No. 1, pp. 57 - 91 (April 1987)(A00498-A00534)			402, F, H
44	*	05/00/87	N. Chand, K. Nolan, W. Diamantis and R.D. Sofia, "Inhibition of acute lung anaphylaxis by aerosolized azelastine in guinea pigs sensitized by three different procedures," Annals of Allergy, Vol. 58, pp. 344-349 (May 1987)(A00535-A00540). (DDX 64 Byrn)			402, F, H

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<b>*</b> 45	09/00/87	J. Dolovich, L. Kennedy, F. Vickerson and F. Kazim, "Control of the hypersecretion of vasomotor rhinitis by topical ipratropium bromide," The Journal of Allergy and Clinical Immunology, Vol. 80, No. 3, Part 1, pp. 274-278 (September 1987)(A00541-A00547).			402, F, H
<b>*</b> 46	00/00/87	O.J. Corrado, S. Ollier, M.J. Phillips, J.M. Thomas and R.J. Davies, "Histamine and allergen induced changes in nasal airways resistance measured by anterior rhinomanometry: reproducibility of the technique and the effect of topically administered antihistaminic and anti-allergi drugs," Br. J. clin. Pharmac., Vol 24, No. 3, pp. 283-292 (1987)(A00548-A00557).			402, F, H
<b>*</b> 47	00/00/87	M. Bende, and U. Pipkorn, "Topical levocabastine, a selective H1 antagonist, in seasonal allergic rhinoconjunctivitis," Allergy, 42, pp. 512-515 (1987)(A00558-A00563).			402, F, H
<b>*</b> 48	00/00/87	W.A.J.J. Hermens and F.W.H.M. Merkus, "The Influence of Drugs on Nasal Ciliary Movement," Pharmaceutical Research, Vol. 4, No. 6, pp. 445-449 (1987)(MPAT000348-MPAT000352)(A00574-A00578).			F
49	00/00/87	G. Feinberg and T.C. Stokes, "Application of Histamine-Induced Conjunctivitis to the Assessment of a Topical Antihistamine, Levocabastine," Int. Archs. Allergy appl. Immun. 82, pp.537-538 (1987)(A00579 - A00580).			402, F, H
<b>*</b> 50	00/00/87	Y.W. Chien and S. Chang, "Intranasal Drug Delivery For Systemic Medications," CRC Critical Reviews in Therapeutic Drug Carrier Systems, Vol. 4, Issue 2, pp. 67-104 (1987)(A00581-A00712).			F
<b>*</b> 51	00/00/87	E.R. Weeke, "Epidemiology of Hay Fever and Perennial Allergic Rhinitis," Monogr. Allergy, Vol. 21, pp. 1-20 (1987)(A00713-A00734).			402, F, H
<b>*</b> 52	06/20/89	U.S. Patent No. 4,841,047 issued June 20, 1989 (A00735 - A00753).			402

<b>*</b> 53	00/00/92	Clinical and Experimental Allergy, 1992, Vol. 22, pages 289-295, "The effect of azelastine on the early allergic response", M.-H. Shin, F. Baroody, D. Proud, A. Kagey-Sobotka, L.M. Lichtenstein and R.M. Naclerio (A00754 - A00762)			402, F, H
<b>*</b> 54	10/08/97	G. Lenhard, E. Mivsek-Music, M. Perrin-Fayolle, K. Obtulowicz and A. Secchi "Randomised, Placebo-controlled Study of Two Concentrations of Azelastine Eye Drops in Seasonal Allergic Conjunctivitis or Rhinocconjunctivitis" Current Medical Research and Opinion, Vol. 14, No. 1 1997 21-28, Double-blind, (A00769 - A00776)			402, F, H
<b>*</b> 55	00/00/98	C. Giede-Tuch, M. Weshoff, A. Zarth "Azelastine eye-drops in seasonal allergic conjunctivitis or rhinocconjunctivitis", Allergy 1998: 53:856-862, (A00777 - A00784)			402, F, H
<b>*</b> 56	06/00/99	W. Berger, MD, MDA, S. Fineman, MD, P. Lieberman, MD, R. Miles, MD and the Rhinitis, Study Groups, "Double-blind trials of azelastine nasal spray monotherapy versus combination therapy with loratadine tablets and beclomethasone nasal spray in patients with seasonal allergic rhinitis", Annals of Allergy, Asthma & Immunology- Volume 82, June, 1999 (A00785 - A00791)			402, F, H
<b>*</b> 57	07/00/99	S. Golden, MS, T. Craig, DO, "Efficacy and safety of azelastine nasal spray for the treatment of allergic rhinitis", JAOA Vol. 99, No. 7, Supp. To July 1999 (A00792 - A00797)			402, F, H
<b>*</b> 58	07/26/01	International Application # WO 01/52828 A1, Pharmaceutical Discovery Corp., S. Steiner (A00798 - A00819)			402, F, H
59	01/00/01	Annals of Allergy, Asthma & Immunology, Volume 86, Jan. 2001, "Efficacy of azelastine nasal spray in the treatment of vasomotor (perennial nonallergic) rhinitis", C. Banov, MD, P. Lieberman, MD for the Vasomotor Rhinitis Study Groups, (A00820 - A00827)			F

60	*	00/00/01	C. Duarte, M. Baehre, S. Gharakhanian, F. Leynadier, and the French Study Group, Treatment of Severe Seasonal Rhinconjunctivitis by a Combination of Azelastine Nasal Spray and Eye Drops: A Double-Blind, Double-Placebo Study", J Invest Allergol Clin Immunol 2001; Vol. 11(1): 34-40, " (A00828 - A00834)			402, F, H
61	*	00/00/05	PDR 59 Ed. 2005, "MedPointe Pharmaceuticals MedPointe Healthcare Inc. (A00835 - A00840)			402, F, H, 106
62		03/30/84	Carter Wallace Report (OPT-MEDA000026 – OPT-MEDA000062)			402, F, H, X
63		06/09/03	OPT-MEDA003093 – OPT-MEDA003094			402, F, H, X
64		12/03/81	European Patent Specification 0055041 B1 (OPT-MEDA000093 – OPT-MEDA000100)			402
65		09/14/84	AS-MEDA0010502 – AS-MEDA0010504			402, F, H
66			K. Thomas, H. Ferguson, S.Ollier R. Davies,"Azelastine Nasal Spray: Effect on Histamineand Allergen Induced Nasal Airways Obstruction (NAR) and sneezing (AS-MEDA0000323)			402, F, H
67			AS-MEDA0010555 – AS-MEDA0010556			402, F, H
68		09/00/88	E. Meltzer MD, W. Storms MD, W. Pierson MD, L. Cummins MD, A. Orgel, MD, PhD, J. Perhach, PhD, and G. Hemworth, PhD, "Efficacy of azelastine in perennial allergic rhinitis: Clinical and rhinomanometric evaluation". J. Allergy Clin. Immunol., Sept. 1988, , Vol. 82 No. 3, Part 1 (A00895 - A00903)			402, F, H
69		06/00/93	R. Naclerio, MD, "The effect of antihistamines on the immediate allergic response: A comparative review", Otolaryngology - Head and Neck Surgery June 1993, Vol. 108, No. 6 (A00904 - A00911)			402, F, H
70		12/00/88	P. Rafferty MRCP, P. Harrison MRCP, R. Aurich and S. Holgate, "The in vivo potency and selectivity of azelastine as an H1 histamine-receptor antagonist in human airways and skin", J. Allergy Clin. Immunol., Dec.1988, FRCP, Volume 82, No. 6 (A00912 - A00917)			402, F, H



71	04/00/87	A. Togias, D. Proud, A. Kagey-Sobotka, P. Norman, L. Lichtenstein and R. Naclerio, "The effect of a topical tricyclic antihistamine on the response of the nasal mucosa to challenge with cold, dry air and histamine," J. Allergy Clin. Immunol., Vol. 79, No. 4, April 1987, pp. 599-604 (A00925-A00930).		402, F, H
* 72	11/00/88	J. Weiller MD, A. Donnelly BA, B. Campbell MD, J. Connell MD, L. Diamond PhD., L. Hamilton PhD, R. Rosenthal MD, G. Hemsworth PhD and J. Perhach, Jr. PhD "Multicenter, double-blind, Multiple-dose, parallel-groups efficacy and safety trial of azelastine, chlorpheniramine, and placebo in the treatment of spring allergic rhinitis", J. Allergy Clin. Immunol, Nov. 1988Vol. 32 No. 5, Part 1 (A00931 - A00941) Meltzer 8		402, F, H
	01/25/82	AS-MEDA0010798 - AS-MEDA0010804		402, F, H
	00/00/90	Drug Facts and Comparisons (SK000280 - SK000289)		402, F, H, 106
75	00/00/86	J. Pharmac. (1986), 87, 443-448, "Modulation of in vitro anaphylaxis of guinea-pig isolated tracheal segments by azelastine, inhibitors of arachidonic acid metabolism and selected antiallergic drugs", (A02322 - A02327)		402, F, H
76	06/00/87	H. Magnussen, MD, "The Inhibitory Effect of Azelastine and Ketotifen on Histamine-induced Bronchoconstriction in Asthmatic Patients", Chest/9/16/June 1987 (A04947 - A04950)		402, F, H
77	06/00/87	J. Kemp MD, E. Meltzer MD, A. Orgel MD, PhD, M. Welch MD, G. Bucholtz MD, E. Middleton, Jr. MD, S. Spector MD, J. Newton MD and J. Perhach, Jr. PhD, "A dose-response study of the bronchodilator action of azelastine in asthma", J. Allergy Clin. Immunol June 1987., Vol 79, No. 6 Meltzer 7		402, F, H
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222			Funktionelle Dermatologie (AS-MEDA0001987-AS-MEDA0001988)			402, F, H
223			Excerpts from Textbook on Dermatology (AS-MEDA0001989- AS-MEDA0001993)			402, F, H, 106
* 224			Excerpt from Martindale The Extra Pharmacopoeia Twenty eighth edition edited by J. Reynolds (AS-MEDA0002009-AS- MEDA0002011)			402, F, H
225			Excerpt from Transnasal Systemic Medications, Fundamentals, Developmental Concepts and Biomedical Assessments, edited by Y. Chien (AS- MEDA0002012-AS- MEDA0002015)			402, F, H
226		10/31/90	ASTA Pharma report: Investigation of long term tolerability of Azelastine HCL nasal spray in patients suffering from perennial allergic rhinitis (AS-MEA0002017- AS- MEDA0002021)			402, F, H
227		10/31/90	ASTA Pharma report: Protection of a single dose of azelastine HCL nasal spray against nasal spray against nasal alterations induced by allergen challenge (AS-MEDA0002028- AS-0002032)			402, F, H
228		05/00/86	Summary of Report of Clinical Trial (AS- MEDA0002059-AS- MEDA0002062)			402, F, H
229		00/00/78	PDR 32 <sup>nd</sup> Edition 1978, Product classification index (AS-MEDA0002105-AS- MEDA0002107)			402, F, H, 106
230		00/00/82	PDR 36 <sup>th</sup> Edition, Product Category Index (AS-MEDA0002108-AS- MEDA0002110)			402, F, H, 106
231		00/00/86	PDR 40 <sup>th</sup> Edition, Product Category Index (AS-MEDA0002111-AS- MEDA0002112)			402, F, H, 106
232		01/01/85	Excerpts from The United States Pharmacopoeia Twentieth First Revision, The National Formulary Sixteenth Edition (AS-MEDA0002113-AS-MEDA0002133)			402, F, H, 106
233		00/00/70	Excerpts from Remington's Pharmaceutical Sciences Fourteenth Edition 1970 (AS- MEDA0002134-AS-MEDA0002145)			402, F, H, 106



234			Study: Investigation of efficacy and tolerability of Azelastine HCL nasal spray during a 6-month-treatment in patients with perennial allergic rhinitis (AS-MEDA0002146-AS-MEDA0002149)			402, F, H
235		02/10/89	ASTA Pharma report: Comparison of the efficacy and tolerability of an azelastine HCL nasal spray with those of terfenadine on six-week treatment of patients with allergic rhinitis (seasonal) (AS-MEDA0002153- AS-MEDA0002157)			402, F, H
236	*	06/07/88	U.S. Patent 4,749,700 (AS- MEDA0002181-AS-MEDA0002195)			402
237		00/00/80	S. Peerless, A. Norman, "Etiology of Otitis Media with Effusion: Antihistamines-Decongestants," The Laryngoscope 90:1980 (AS-MEDA0002250-AS-MEDA0002262)			402, F, H
238		07/29/80	European Patent Application 0 023 359 A2 (AS-MEDA0002275-AS- MEDA0002315)			402, F, H
239		00/00/87	S. Katayama, H. Tsunoda, Y. Sakuma, H. Kai, I. Takana, K. Katayama, 'Effect of Azelastine on Release and Action of Leukotriene C4 and D4," Int. Archs Allerhy appl. Immun 83:284-289 (1987) AS-MEDA0002335 – AS-MEDA0002340)			402, F, H
240		02/10/89	ASTA Pharma report: Investigation of the efficacy and tolerability of an azelastine HCL nasal spray during a 6-month treatment in patients with perennial allergic rhinitis (AS- MEDA0002364-AS- MEDA0002397)			402, F, H
241			Study: ASTA Pharma report: Comparison of the efficacy and tolerability of an azelastine HCL nasal spray with those of terfenadine on six-week treatment of patients with allergic rhinitis (seasonal) (AS- MEDA0002400- AS-MEDA0002402)			402, F, H
242			Hals-Nasen-Ohren-Heilkunde (AS-MEDA0002440-AS-MEDA0002441)			402, F, H
243			Hals-Nasen-Ohren-Heilkunde (AS-MEDA0002442-AS-MEDA0002445)			402, F, H



244		Excerpts from Deutsches Arzneibuch (AS-MEDA0002458-AS-MEDA00002468)			402, F, H, 106
245	10/15/90	ASTA Pharma report: Solubility of Azelastine HCL dependent on ph-value, chloride concentration and temperature (AS- MEDA0003186 – AS-MEDA0003189)			402, F, H
246		Allgemeine Texte (AS- MEDA0003541-AS-MEDA0003547)			402, F, H
247	01/06/86	Handwritten notes (AS-MEDA00004180- AS-MEDA0004181)			402, F, H
248		Handwritten notes (AS-MEDA00004247- AS-MEDA0004248)			402, F, H
249	08/20/86	Memo from D. Hettche to Dr. Aurich (AS- MEDA0005005)			402, F, H
250	08/06/86	Memo from D. Hettche to Dr. Teubner (AS- MEDA0005006)			402, F, H
251	09/06/85	Memo to Dr. Hettche (AS- MEDA0005014- AS-MEDA0005015)			402, F, H
252	08/16/90	ASTA Pharma report: Compatibility of different Buffer Systems with Benzalconium chloride in Azelastine Hydrochloride Intranasal Spray (AS-MEDA0005164- AS-MEDA0005170)			402, F, H
253	02/03/87	Memo from Dr. Hettche to Dr. Jahn (AS-MEDA0005219)			402, F, H
254	02/22/88	ASTA Pharma Expert Report: Chemical and Pharmaceutical Documentation according to section 24 (1) AMG 1976 Azelastine Intranasal Spray (AS-MEDA0005650-AS-MEDA0005674)			402, F, H
255	09/13/88	ASTA Pharma report: Development of Pharmaceuticals of Azelastine Hydrochloride 0.1% Nasal Spray (AS-MEDA0005735- AS- MEDA0005738)			402, F, H
* 256		Excerpt from Biopharmazie (AS MEDA0005739- AS-MEDA0005741)			402, F, H
257	01/03/92	Memo from Dr. Hettche to Dr. Nagl re: Azelastin Nasenspray / Verpackung fur Ausland (AS-MEDA0005955)			402, F, H
258	11/1/90	Final Protocol – The Effect of Intranasal Azelastine on the Symptoms and Signs of Nasal Allergy Demonstrated in Patients with Perennial Allergic Rhinitis (AS-MEDA0006741- AS- MEDA0006793)			402, F, H

259	02/06/92	A multicentre, single-blind safety and efficacy study of intranasal azelastine versus intranasal levocabastine in patients with seasonal allergic rhinitis (AS-MEDA0006823- AS- MEDA0006824)			402, F, H
260	01/16/92	Memo rom Dr. Bahre to Dr. Hettche re: Azelastine – Nasenspray vs. Levocabastine (AS- MEDA0006853)			402, F, H
261	04/13/87	Summary Report of Clinical Trial (AS- MEDA0007026- AS- MEDA0007030)			402, F, H
262	05/15/889	Trial/Study: The Effect of Intranasal Azelastine on Nasal Airways Obstruction Following Provocation Testing with Histamine and Allergen (AS-MEDA0007612- AS-MEDA0007636)			402, F, H
263		Summary of Facts and Submissions (AS-MEDA0008513- AS-MEDA0008527)			402, F, H
264	07/05/98	Decision from the European Patent Office (AS-MEDA0008528- AS- MEDA0008533)			402, F, H
265	09/07/81	Decision from the European Patent Office (AS-MEDA0008534- AS- MEDA0008539)			402, F, H
266	04/05/94	Letter from Dr. Merk and Dr. Teubner (AS-MEDA0008546- AS- MEDA0008550)			402, F, H
267	04/05/00	(AS- MEDA0008656-AS-MEDA0008666)			402, F, H
268	02/04/99	Decision of the Technical Board of Appeal 3.3.2 of 4 February 1999 (AS- MEDA0008710- AS- MEDA0008725)			402, F, H
269	08/07/96	Letter from G. Bezold (AS- MEDA0008742-AS-MEDA0008753)			402, F, H
270		(AS- MEDA0008812- AS- MEDA0008830)			402, F, H
271		(AS- MEDA0008877- AS- MEDA0008891)			402, F, H
272	02/04/99	Decision of 4 February 1999 (AS- MEDA0009089-AS-MEDA0009090)			402, F, H
273		(AS- MEDA0009128)			402, F, H
274		Sales History: Europe Only- Nasal Spray (AS-MEDA0009129)			402, F, H
275		Number not used			N/A
276	09/00/51	L. Gundrum, "Experimental Investigations on Action of Histaminic Nasal Solutions," California Medicine, Vol 75. No. 3. September, 1951 (Meltzer 12)			NONE

277	08/09/86	Excerpts from Deutsches Arzneibuch (AS-MEDA0009604- AS- MEDA0009607)			402, F, H
278	08/12/87	Memo from Dr. Hettche to Dr. Ulbrich re: Azelastin Nasenspray: Prufung bei Schnupfen (AS- MEDA0009737)			402, F, H
279	09/06/85	(AS- MEDA0009738)			402, F, H
280		German Patent 33 02 949 A1 (AS- MEDA0009821-AS-MEDA0009834)			402
281	03/03/87	Memo from Dr. Herbst to Dr. Hettche re: Azelastin-Nasenspray (AS-MEDA0009915)			402, F, H
282	09/15/86	Memo from Dr. Aurich re: Azelastin-Nasenspray (AS-MEDA0009922)			402, F, H
283	08/06/86	Memo from Dr. Aurich to Dr. Hettche re: Azelastin-Nasenspray (AS-MEDA0009923)			402, F, H
284	09/06/85	Memo from Dr. Aurich to Dr. Hettche re: Azelastin-Nasenspray (AS-MEDA0009925)			402, F, H
285	06/05/87	Memo from Dr. Aurich to Dr. Hettche re: Azelastin-Nasenspray (AS-MEDA0009934)			402, F, H
286	00/00/84	T. Fukada, T. Saito, M. Yoshidomi, K. Ito, "Influence of 1-(2-Ethoxyethyl)-2-(4-methyl-1-homopiperazinyl)benzimidazole Difumarate (KB-2413), a New Antiallergic, on Ciliary Movement," Arzneimittel-Forsch., Drug Res. 34, pp. 816-818 (1984) AS-MEDA0010111-AS-MEDA0010113			F
287	02/00/95	C. Baumgarten, U. Fetzold, D. Dokic, R. Aurich, G. Kunkel, "Modification of Allergen-induced Symptoms and Mediator Release by Intranasal Azelastine," Journal of Pharmacology 2/94 (AS- MEDA0010148- AS-MEDA0010156)			402, F, H
288		(AS-MEDA0010472)			402, F, H
289		(AS-MEDA0010480 - AS-MEDA0010484)			402, F, H
290	03/30/84	Carter Wallace Report: Placebo and Positive Controlled Comparison of the Tolerability and Efficacy of Three Doses of Azelastine and Fixed Dose of Chlorpheniramine Maleate in Seasonal Allergic Rhinitis – Spring 1983 (OPT-MEDA0000026 – OPT-MEDA0000062)			402, F, H, X

291		Number not Used				N/A
292	02/16/87	Declaration under Rule 132 by Dr. Achterrath-Tuckermann dated February 16, 1987				402
293	05/05/87	Developmental Research Carter-Wallace/Degussa Meeting Frankfurt Germany (AS0000745-AS0000815)				402, F, H
294		Presentation: Protective Efficacy of Azelastine HCI Nasal Spray (AS0000858-AS0000866)				402, F, H
295		Dr. L. C. Wang, Ms. A. Chao, "Spray Droplet Size of Azelastine Nasal Solution" Method and Specification Development (AS0000868-AS0000885)				402, F, H
296	05/15/90	Letter from S. Gordzie to Dr. Goede re: Enclosure of comments on the draft minutes (AS0000905-AS0000931)				402, F, H
297	02/26/90	Memo from Dr. Fields enclosing the minutes from the 9/89 Wallace/ASTA Joint Scientific meeting in Frankfurt (AS0000959-AS0000978)				402, F, H
298	02/09/90	Follow up activities: Scientific Meeting ASTA Pharm/CVarter Wallace on September 14 <sup>th</sup> /15 <sup>th</sup> , 1989 (AS0000982-AS0000985)				402, F, H
299	12/12/89	Memo from Dr. Fields enclosing the draft meeting minutes of the September 14-15, 1989 Wallace ASTA joint scientific meeting (AS0000992-AS0001010)				402, F, H
300	04/17/89	Memo from E. Bohrer re: Minutes of the December 8-9 Wallace/ASTA Developmental Research Satellite Meeting (AS001069-AS001101)				402, F, H
301	11/30/87	Handwritten notes (AS0001760-AS001761)				402, F, H
302	05/00/87	Handwritten notes (AS0001901-AS001913)				402, F, H
303	07/2589	Memo from D. Fields to J. Perach, J. Rapoza, D. Sofia re: meeting with DR. Engel 7/18/89 (AS0001993-AS0001994)				402, F, H
304	07/06/83	Letter from Dr. Engel to Dr. McKenzie re: Enclosure of solubility report of Azelastine and Azelastine-Salts (AS002172-AS002181)				402, F, H
305	09/03/90	Memo from E. Bonner re: Azelastine Project (AS0002199-AS002205)				402, F, H

306	02/01/91	Wallace Laboratories report: Formula Rationale for Azelastine Hydrochloride Nasal Solution 0.1% w/v (AS002526-AS002546)				402, F, H
307	02/21/90	Memorandum from J. Bodin to Dr. Gordziel re: Azelastine Nasal Spray (AS002615-AS002623)				402, F, H
308	02/08/90	Memorandum from Dr. Wang to Dr. Bodin re: Azelastine Nasal Spray (AS002644- AS002649)				402, F, H
309	05/25/98	Draft letter: Azelastine Hydrochloride 0.1% Nasal Spray (AS002664- AS002665)				402, F, H
310		Excerpt from Aerosols in Medicine Principles, Diagnosis & Therapy (AS0002667- AS0002669)				402, F, H, 106
311	06/09/92	Memorandum from A. Chao to Dr. Wang re: Specification of Droplet Size for Azelastine Nasal Spray (AS0002920- AS002923)				402, F, H
312	09/07/90	Letter from Dr. Hettche & Dr. Molliere to Dr. Gordziel re: Enclosure of publication (AS0002995- AS0003013)				402, F, H
313		Memorandum of Record: Telephone contact with Dr. Hettche, Manager Formulations, Degussa Pharma, Germany (AS0003146- AS0003147)				402, F, H
314	04/28/89	Memorandum from M. Bielant to Dr. Diamantis & Dr. Gordziel re: ASTA document – Azelastine HCL (AS0003184- AS0003193)				402, F, H
315	04/16/97	Minutes: Azelastine project Team Meeting No. 43 (AS0004108 – AS0004136)				402, F, H
316	07/02/92	Letter from E. Matarese to B. Wilson re: Enclosure of test results (AS0003447- AS0003468)				402, F, H
317	01/05/90	Memorandum from Dr. Wang to Dr. Bodin re: Droplet Size Pattern Nasalide Nasal Spray in Syntex and Valois Metered Dose Nebulizers (AS0003558- AS0003560)				402, F, H
318	12/14/89	Memorandum from Dr. Wang to Dr. Bodin re: Droplet Size Pattern Nasalide Nasal Spray in Syntex and Valois Metered Dose Nebulizers (AS0003572- AS0003577)				402, F, H
319	11/20/91	Amendment to research report (AS0004236- AS0004237)				402, F, H
320	01/03/91	Wallace Laboratories report: Formula Rationale for Azelastine Hydrochloride Nasal Solution 0.1% w/v (AS004850-AS004860)				402, F, H



321	11/24/92	Letter from D. Auslander to Dr. Heitche re: topics to be discussed on December 4 <sup>th</sup> . (AS0005080 – AS0005082)			402, F, H
322	10/24/90	Wallace Laboratories report: Solubility of Azelastine Hydrochloride in Azelastine Hydrochloride Nasal Solution (AS0005433- AS0005437)			402, F, H
323	09/24/90	Wallace Laboratories report: Validation of the Liquid Droplet Sizing Method for Azelastine Hydrochloride 0.1% Nasal Spray (Valois Pumps) Using the Malvern Particle Analyzer (AS0005452- AS0005476)			402, F, H
324	00/00/88	A. Mitra, S. Gordziel, "Characterization of Hydration / Solvation Characteristics of Azelastine Hydrochloride," Drug Development and Industrial Pharmacy, 14(7) 953-975 (1988) (AS0005732- AS0005754)			402, F, H
325	08/14/84	Wallace Laboratories report: Azelastine Hydrochloride: pH vs. Solution Stability (AS0005799- AS0005805)			402, F, H
326	09/25/92	Wallace Research & development Department Presentation to Scientific Advisory Board; September 25, 1992 (AS0006195-0 AS0006200)			402, F, H
327		Azelastine Pharmacological Profile (AS0006209- AS0006213)			402, F, H
328	06/26/90	ASTA Pharma report: Azelastine Investigational Drug Brochure (AS0006334- AS0006415)			402, F, H
329	07/27/90	Letter from I. Szelenyi to D. Sofia (AS0006416)			402, F, H
330	07/06/92	Memorandum from M. Biela re: Azelastine-Publications List (AS0006485- AS0006535)			402, F, H
331	02/13/90	Amendment No. 1 to ASTA Pharma report LC-5505 (AS0006544- AS0006546)			402, F, H
332	07/11/89	Memorandum from K. Bielat to D. Fields, J. Freitag, S. Gordziel & J. Perach re: ASTA documents- Azelastine (AS0006586 – AS0006589)			402, F, H
333	08/24/88	Memorandum from N. Ivins to Dr. McGee re: GLP Audit of the Final Draft report (AS0006614 – AS0006640)			402, F, H
334	07/07/89	Wallace Laboratories report: Six –Month Intranasal Toxicity study of Azelastine Hydrochloride in the Albino rat (AS0006658- AS0006668)			402, F, H

335	01/31/91	ASTA Pharma report: A Two0Week Comparative Study of The Safety and Efficacy of Azelastine Nasal Spray in the Management of Seasonal Allergic Rhinitis (AS0006703 – AS0006714)			402, F, H
336	03/09/90	ASTA Pharma report: Protection of Azelastine.HCL nasal spray against nasal alterations induced by allergen challenge (AS0006722- AS0006726)			402, F, H
337	06/30/90	ASTA Pharma report: Inhibition of histamine –induced nasal hypersecretion by azelastine following local application (AS006727- AS006747)			402, F, H
338	11/18/91	Listing of ASTA's clinical studies (AS0006765- AS006769)			402, F, H
<b>*</b> 339		Astelin net sales: January 1997- June 2006 (AS0006777- AS0006779)			NONE
<b>*</b> 340		AS0006780- AS0006833			NONE
341	12/01/03	Letter from R. Fosko to the FDA re: Request for clarification (AS0006871- AS0006877)			402, F, H
342	03/03/04	Facsimilie from the FDA to R. Fosko re: February 3, 2004 teleconference (AS0006900- AS0006903)			402, F, H
<b>*</b> 343	08/16/02	Assignment and Assumption Agreement (AS0007016- AS0007027)			402
<b>*</b> 344	11/01/97	Schedule E: Assignment and and Assumption Agreement (AS0007028- AS0007033)			402
<b>*</b> 345	11/01/97	Exhibit B: License Agreement (AS0007034- AS0007036)			402
<b>*</b> 346	11/01/97	Exhibit : Amendment to Azelastine License Agreement (AS0007037-AS0007038)			402
<b>*</b> 347	07/31/96	Letter from D. Black to DR. Engel re: August 16, 1982 License Agreement (AS0007039- AS0007040)			402
<b>*</b> 348	04/11/01	Amendment to August 16, 1982 License Agreement (AS0007041- AS0007042)			402



349	*	05/17/02	Interest Purchase Agreement (AS0007045- AS0007067)			402
350	*	05/17/02	Exhibit A: Agreement (AS007068- AS007079)			402
351	*	05/17/02	Schedule III: Patent Assignment (AS0007080- AS0007085)			402
352	*		Schedule IV: 07/31/96 letter to Dr. Engel (AS0007086- AS0007088)			402
353	*	08/16/92	License Agreement between Homburg & Degussa (AS007908- AS0007950)			402
354		08/30/90	Meeting minutes of the 04/19-20/90 Wallace/ASTA joint scientific meeting (AS0007124- AS0007171)			402, F, H
355	*	02/27/87	Telefax from D. Fields to Dr. Engel re: Enclosure of meeting minutes (AS0007208- AS0007235)			402, F, H
356		03/29/88	Meeting minutes of the 11/30-12/01/87 Wallace/ASTA joint scientific meeting (AS0007236- AS0007274)			402, F, H
357		04/22/92	Meeting minutes of the 10/31-11/01/91 Wallace/ASTA joint scientific meeting (AS0007281- AS0007333)			402, F, H
358		08/18/89	Highlight of the July 16, 1989 Developmental Research Azelastine Project Meeting (AS0007419- AS0007423)			402, F, H
359		05/10/89	Memo from E. Bohrer re: May 3, 1989 Developmental Research Azelastine Project meeting (AS0007424- AS0007444)			402, F, H
360		02/25/87	Meeting minutes (AS0007445- AS0007471)			402, F, H
361		01/24/06	Apotex's Paragraph IV Letter (AS0007855- AS0007883)			NONE
362		10/02/89	Memorandum from Dr. Gordziel & Dr. Mortko re: ASTA Pharma Scientific Meeting 09/14-15/89) (AS0007890 – AS0007895)			402, F, H
363	*		Astelir net sales; January 1997- May 2007 (AS0007951- AS0007954) (DDX 57 Hostler)			NONE
364	*		Data Report from IMS Health re: Total Astelin prescriptions (AS0007955- AS0007957) (DDX 60 Hostler)			NONE

365	*			Data Report from IMS Health re: Total Astelin Prescriptions (AS0007958- AS0007960) (DDX 59 Hostler)			NONE
366	*			Data Report from IMS Health re: New Astelin Prescriptions (AS00007961- AS0007965) (DDX 58 Hostler)			NONE
367		12/18/01		Master Services Agreement between MedPointe & Wallace (AS0007966- AS0007983)			402, F, H
368		08/05/02		Letter from MedPointe to Sepracor, Inc. re: proposed co promotion arrangement (AS0007984- AS0008047)			402, F, H
369		06/08/98		Agreement between Carter-Wallace and Syncom (AS0008048- AS0008075)			402, F, H
370		03/31/98		Wallace Laboratories – Financial Statements for the 12 <sup>th</sup> Month ending 03/31/98 (AS0008076- AS0008255)			402, F, H
371		03/01/01		Wallace Laboratories – Financial Statements for the 12 <sup>th</sup> Month ending 03/01/01 (AS0008256- AS0008255)			402, F, H
372		03/31/04		Medpointe Pharmaceuticals Financial Statements for the Twelve Months ending 03/31/04 (AS0008428 -- AS0008620)			402, F, H
373				New Drug Application: ASN000000001 – ASN00221537			402
373A		03/26/91		Letter from Wallace laboratories to the FDA re: NDA20114 (ASN000000006 -- ASN000000009)			402, 1006
373B				NonClinical Pharmacology and Toxicology Summary (ASN00000353 – ASN04000437)			402, 1006
373C		00/00/80		M. Okuda, et al., Oto-Rhino-Laryngology Tokyo, Vol 23, Suppl. 6, pp. 441-461 (1980)(A00254-A00275)(with English summary provided by Carter-Wallace to the FDA at 08 35301 – 08 35313) See ASN00074575-ASN00074587			402, F, H
374				Initial New Drug Application: ASI0000000001 -- ASI00005368			NONE
374A				Investigator's Brochure (ASI000000023 – ASI000000147)			402, 1006
374B		01/22/90		Letter from Wallace Laboratories to the FDA (ASI00003249 – ASI00003399)			402, 1006
374C				Item C from the General Investigational Plan (ASI00004058 – ASI00004060)			402, 1006

374D			Item B from the General Investigational Plan (ASI00004087 – ASI00004106)			402, 1006
375			Initial New Drug Application for Azelastine Tablets: AT100000001 – AT100002428			402
375A		09/23/80	Wallace Laboratories Report: AT100000919 – AT100000947)			402, 1006
376		11/16/90	Asta Pharma Report, "Comparison of efficacy and tolerability of azelastine nasal spray, azelastine tablets and astemizole in the treatment of seasonal allergic rhinitis," (MPAT0000490 – MPAT000494)			402, F, H
* 377		1996	R.J. Davies, A.C. Bagnall, R.N. McCabe, M.A. Calseron, and H.J. Wang, "Antihistamines: topical v.s oral administration," Clinical Experimental Allergy, 1996 Voil. 26 Suppl 3, ppgs. 11-17 (including front cover and copyright pages) (ASC0000062 – ASC0000070)			402, F, H
* 378		06/00/94	W.W. Storms, D.S. Pearlman, P.O. Chervinsky, J. Grossman, P.C. Halverson, J.J. Freitag and M.D. Widlitz, "Effectiveness of Azelastine Nasal Solution in Seasonal Allergic Rhinitis," ENT, Vol 73 No. 6 (June 1994), pp. 382- 394 (including front cover and copyright page) (ASC0000169-ASC0000179)			402, F, H
* 379		10/00/97	D.Wang, J. Smitz, M. De Waele, and P. Clement, "Effect of Topical Applications of Budesonide and Azelastine on Nasal Allergen Challenge during Pollen Season," Int Arch Allergy Immunol 1991; 114:: 185-192 (October 1997) (including front cover and copyright page) (ASC0000203 – ASC0000212)			402, F, H
* 380		02/26/07	Medical News Today: Steroid-Free Astelin® Nasal Spray® Demonstrated Seasonal Allergy Symptom Improvement Within 15 Minutes in Clinical Study (ASC0000229- ASC0000230)			NONE
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383		Product insert for Migranal (A08349- A08350)			402, F, H
384	06/22/86	U.S. Patent 4,602,099 (A08351- A08358)			402
385	00/00/82	Handbook of Nonprescription Drugs 7 <sup>th</sup> edition (cover page, table of contents, pps 166- 169; 428 – 430) (A08359- A08371)			
386	02/26/85	U.S. Patent 4,501,893 (A08372- A08378)			402, F, H
		X. Su, A. Po, "The effect of some commercially available antihistamine and decongestant intra-nasal formulations on ciliary beat frequency," Journal of Clinical Pharmacy and Therapeutics (1993) 18, 218-222 (A08339- A08342)			402
387	00/00/93	Curriculum Vitae of Maureen D. Donovan, Ph.D.			402, F, H
388		Curriculum Vitae of Ronald H. Smith			F, H
389		Curriculum Vita of Howard J. Schwartz M.D.			402, F, H
390		Amended Complaint			F, H
391	03/13/06	Answer to the Amended Complaint			NONE
392	04/14/06	Rule 16 Scheduling Order			NONE
393	06/16/07	Deposition transcript of Naresh Chand			402
394	04/18/07	N. Chand, "Inhibition of Allergic and Nonallergic Histamine Secretion by Azelastine, Its Putative Metabolites and Analogs in Rat Peritoneal Mast Cells and Rabbit Mixed Leukocytes (Basophils), Wallace Laboratories, Pharmacology, PH-84-6, February 27, 1984 (ASN00003646 – ASN00003665) (PDX 1 Chand)			402, F, H, 32
394A	02/27/84	Wallace Laboratories Report (ASN00003727 – ASN00003744) (PDX 2 Chand)			
394B		Letter from S. Benson to LaSalle Process Servers (DDX 14 Chand)			402, F, H
3943C	04/02/07	U.S. Patent No. 3,813,384 issued May 28, 1974 (A00133 – A00138)(A06652 – A06657). *			402, F, H
394D	05/28/74	(DDX 15 Chand, Meltzer 5)			402
394E	11/17/92	U.S. Patent 5,164,194 issued November 17, 1992 (A00763 - A00768) (DDX 16 Chand)			NONE

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394O	02/21/07	N. Chand, K. Nolan, W. Diamantis and R.D. Sofia, "Effect of Aerosolized Azelastine on Acute Lung Anaphylaxis in Guinea Pigs (GP) Sensitized by Two Different Procedures," The Pharmacologist, Vol. 27, No. 1 (1985)(Abstract 76)(DDX 26Chand) CH0111 – CH0113)(A05995)			402, F, H
395		Article: Bestehen dosisabhängige Wirkungsunterschiede bei der topischen Therapie mit dem H-Rezeptor-Antagonisten Azelastin? (OPT-MEDA000063 – OPT-MEDA000068)			402
396	03/09/07	Plaintiff's First Amended Rule 26(a)(1) Initial Disclosures (DDX 3 Fishman)			NONE
397	01/14/02	News Release: Medpointe Announces Sales Force Expansion and Agreement with Innovex. (DDX 8 Fishman)			402, F, H
398	08/20/02	News Release: Medpointe Announces Astelin Co-Promotion Agreement With Sepracor. (DDX 9 Fishman)			402, F, H
399	09/09/02	News Release: Medpointe Acquires 100% of Astelin Rights in US and Canada. (DDX 10 Fishman)			402, F, H
400	04/30/04	News Release: Medpointe and Sepracor Agree to Phase out Astelin Co- Promotion. (DDX 11 Fishman)			402, F, H
401	02/14/06	News Release: Medpointe Launches Astelin Investment Campaign. (DDX 12 Fishman)			402, F, H
* 402	10/08/03	Patent Security Supplement (MPAT 0000224- MPAT 0000230)			402, F, H
403	06/14/07	Deposition transcript of R. Duane Sofia			402, F, H, 32
403A	04/24/07	Letter from S. Benson to LaSalle Process Servers (DDX 27 Sofia)			402
403B	12/09/88	Minutes: Wallace/ASTA Developmental Research Satellite Meeting December 8-9, 1988 Cranbury, New Jersey (AS001377- AS001408) (DDX 28 Sofia)			402, F, H

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403C	11/21/83	Memorandum of Record: Minutes of Meeting with Dr. J. Engel, Degussa Pharma (AZ000007- AZ000012) (DDX 29 Sofia)			402, F, H
403D	06/12/07	Webpage printout for Eisai Co. Ltd (DDX 30)			402, F, H
403E		Azeptin Information Sheet (DDX 31 Sofia)			402, F, H
403F	10/09/07	Memorandum from Dr. Gordziel re: Carter-Wallace-Degussa November 1987 Scientific Meeting (AS0001681-AS0001758) (DDX 32 Sofia)			402, F, H
403G	06/06/97	Minutes: Wallace/Degussa Joint Scientific Meeting and Toxicology and Pharmaceutical Development Satellite Sessions May 4-6, 1987 Frankfurt, West Germany (AS001832-AS001856) (DDX 33 Sofia)			402, F, H
403H	06/03/83	Memorandum from D. Sofia to F. Stiefel re: Azelastine Derivatives, Metabolites and Salts (AZ0000552) (DDX 34 Sofia)			402, F, H
403I	01/16/90	Memorandum from Dr. Gordziel to Dr. Sofia re: ASTA/AWallace Scientific Meeting, April 1990; Proposed Agenda (AS000740- AS000741) (DDX 35 Sofia)			402, F, H
403J	03/09/90	Telefax from D. Fields to J. Respondek re: enclosure of 02/27/90 draft meeting minutes (AS0001995-AS0002001) (DDX 36 Sofia)			402, F, H
403K	1970	Excerpts from Remington's Pharmaceutical Sciences. (DDX 37 Sofia)			402, F, H, 106
404	08/06/06	Expert Report of Eli Meltzer			H
405	09/10/07	Opposition Expert Report of Eli Meltzer			H
406	08/06/06	Expert Report of Stephen Byrn			H
407	09/1/07	Opposition Expert Report of Stephen Byrn			H
408	08/06/06	Expert Report of Richard Dalby			H
409	09/10/07	Opposition Expert Report of Richard Dalby			H
410	07/01/02	News Release: Medpointe Announces Appointment of Experienced Medical/Regulatory Affairs Executive, Richard N. Spivey. (DDX 38 Spivey)			402, F, H
411		Astelin Product Inset (DDX 40 Spivey)			402, F, H



412	08/16/04	News release: Astelin (Azelastine Hydrochloride) Nasal Spray Effective in Patients Whose Allergy Symptoms Responded Inadequately to Treatment With Allegra. (DDX 41 Spivey)			402, F, H
413	05/11/05	News release: Astelin (Azelastine Hydrochloride) Nasal Spray Provided Greater Improvement in Relieving Nasal Allergy Symptoms than Zyrtec. (DDX 42 Spivey)			402, F, H
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* 417		J. Corren, W. Storms, J. Bernstein, W. Berger, A. Nayak, H. Sacks, "Effectiveness of Azelastine Nasal Spray Compared with Oral Cetirizine in Patients with Seasonal Allergic Rhinitis, Clinical Therapeutics May 2005 (ASC0000049 – ASC0000049)			F, 106
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419	05/30/07	Apotex's Amended Notice of Deposition of Medpointe Healthcare Inc. Pursuant to Fed R.Civ. 30(b)(6) (DDX 51 Sacks)			402
420	06/29/07	Plaintiff's Objections & supplemental Response to Apotex's Interrogatory No. 14 (DX 52 Sacks)			H

421			Documents cited in Plaintiff's Objections & Supplemental Responses to Apotex's Interrogatory NO. 14 Volume 1 (DDX 53 A French)			H
422			Documents cited in Plaintiff's Objections & Supplemental Responses to Apotex's Interrogatory NO. 14 Volume 2 (DDX 53 B French)			H
423	12/22/04		Medpointe Record Retention Policy (AS00000642 -- AS00000665) (DDX 54 French)			402, F, H
424			Document re: location of Carter-Wallace files (DDX 55 French)			402, F, H
425			Binder containing documents reviewed by Hostler (DDX 57 Hostler)			402, F, H
426	07/20/07		Press Release: Meda Enters the US Market through the strategic acquisition of Medpointe Inc (DDX 61 Hostler)			402, F, H
427	00/00/87		PDR 41 <sup>st</sup> Edition 1987, Product information index (DDX 66 Byrn)			402, F, H
428	00/00/07		Medco documents re: Migraine Agents (DDX 67 Byrn)			402, F, H
429			Copy of Astelin Box (Meltzer 6)			NONE
430	10/00/79		Important Advances in Clinical Medicine: Epitomes of Progress -- Allergy; The Western Journal of Medicine (Meltzer 9)			402, F, H
431	00/00/83		Excerpt from Allergy Volume two Principles and Practice (Meltzer 16)			402, F, H
432	11/24/04		Certified File Wrapper for 60/630,274 (MP2501 -- MP2536)			402
433	08/06/07		Expert report of Dr. Robert Langer			F, H
433A			Langer Tab 1: Curriculum Vitae of Robert Samuel Langer			F, H
433B			Langer Tab 2: Article form Journal of Pharmaceutical Sciences			402, F, H
433C			Langer Tab 3: Astelin product insert			402, F, H
433D			Langer Tab 4			F
434	10/15/07		Supplemental Report of Dr. Robert Langer			F, H
434A			Langer Tab A: United States Patent: 4,602,909			402
434B			Langer Tab B: Plaintiff's Objections and Supplemental Response to Apotex's Interrogatory No. 14			NONE
434C			Langer Tab C: Article from American Family Physician			402, F, H

434D			Langer Tab D: Medco document			402, F, H
434E			Langer Tab E: Langer Laboratory Document			402, F, H
434F			Langer Tab F: MPAT0000277			402, F, H, 106
434G			Langer Tab G: MPAT0000404			402, F, H, 106
434H			Langer Tab H: Asta Pharma Document (AS-MEDA0003522 -- AS-MEDA0003525)			402, F, H
434I			Langer Tab I: MPAT0000187			402, F, H
435						402, 403, F, H, Untimely, Inappropriate Expert Testimony
436	08/06/07		Second Supplemental Report of Dr. Robert Langer Expert Report of Maureen D. Donovan			F, H
437			Supplemental Expert Report of Maureen Donovan			402, 403, F, H, Untimely, Inappropriate Expert Testimony
438			German Patent Application 35 39 873 (priority document for '047 patent) (A05397-A05452) (A05457 -- A05505)			402, F, H
439	11/21/1983		Memorandum re Meeting with Dr. J. Engel (AZ00000007 -- AZ00000012)			402, F, H
440	12/04/1984		Handwritten Notes re Degussa Meeting (AZ00000017 -- AZ00000031)			402, F, H, A
441	12/20/1984		Memorandum re Meeting with Chemiewerk Homburg and Organon (AZ0000102 -- AZ0000109)			402, F, H
442	08/25/1987		Letter to Dr. Sophia re Azelastine Hydrochloride (AZ0000175 -- AZ0000176)			402, F, H
443			Asta Medica Report re Azelastine Eye Drops (AZ0000186 -- AZ0000192)			402, F, H
444			Report re Azelastine Cream (AZ0000193 -- AZ0000195)			402, F, H
445			Report and Test Results re Azelastine (AZ0000200 -- AZ0000224)			402, F, H
446	08/10/1989		Letter re Draft Agenda for September 1989 Wallace/Asta Joint Scientific Meeting (AZ0000225 -- AZ0000229)			402, F, H

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447	12/8/1988	Agenda for Wallace/ASTA Joint Developmental Research Meeting (AZ0000233 – AZ0000237)			402, F, H
448	02/00/1983	Report re Physiochemical Properties of Azelastine Hydrochloride (AZ0000240 – AZ0000266)			402, F, H
449	04/08/1987	Letter to Dr. S. Gordziel re Samples and Documents (AZ0000267 – AZ0000268)			402, F, H
450		Handwritten Notes re Azelastine Development (AZ0000269 – AZ0000270)			402, F, H
451	08/00/1991	Asta Medica Report re Azelastine Cream (AZ0000306 – AZ0000340)			402, F, H
452	03/16/1987	Letter to Dr. Gordziel (AZ0000368)			402, F, H
453	05/12/1986	Letter to Dr. Gordziel re Azelastine Samples (AZ0000369 – AZ0000373)			402, F, H
454	08/24/1985	Report re Azelastine Formulations (AZ0000375 – AZ0000379)			402, F, H
455	11/08/1983	Letter re Questions About Azelastine HCL Dosage Forms (AZ0000380)			402, F, H
456	11/9/1983	Letter in Response to Questions About Azelastine HCL Dosage Forms (AZ0000381 – AZ0000390)			402, F, H
457	09/28/1983	Letter to Dr. Gehringer re Several Drugs Including Azelastine (AZ0000409 – AZ0000411)			402, F, H
458	07/25/1988	Minutes re Azelastine Project Team Meeting No. 57 (AZ0000417 – AZ0000422)			402, F, H
459	07/23/1987	Memorandum re Azelastine (AZ0000497 – AZ0000500)			402, F, H
460	09/24/1986	Memorandum re Azelastine Taste Mask Trials (AZ0000501 – AZ0000502)			402, F, H
461	01/11/1984	Memorandum re Azelastine Requirements (AZ0000537 – AZ0000538)			402, F, H
462	01/27/58	German Patent:1178975 (OPT-MEDA000121 – OPT-MEDA000126)			402
463	06/30/1988	Various Documents re Azelastine Composition (AZ0000574 – AZ0000583)			402, F, H
464	06/05/1990	Memorandum re Azelastine Ophthalmic and Topical Formula (AZ0000794 – AZ0000797)			402, F, H

465	01/05/1922	Physiological Tests of Nose Drops by C. Gallay (Pharmaceutica Acta Helveticae 35, 358-374 (1960) (AZ0000799 – AZ0000819)			402, F, H
466		Typewritten Notes re Conversation on 6/19/1900 with Dr. Hettche re Azelastine Nasal Spray, Eye Drop and Cream (AZ0000824)			402, F, H
467	09/00/1989	Asta Pharma Report re Topical Formulations of Azelastine For Tests in Animals (AZ0001031 - AZ0001033)			402, F, H
468	11/01/1991	Memorandum re Azelastine Suspension (AZ0001212 – AZ0001213)			402, F, H
469	06/08/1992	Memorandum re Astelin Nasal Spray (AZ0001218 – AZ0001219)			402, F, H
470	06/30/1989	Memorandum re Azelastine Project (AZ0001414 – AZ0001431)			402, F, H
471	04/24/1989	Memorandum re Azelastine Project (AZ0001492 – AZ0001511)			402, F, H
472	09/00/1989	Asta Pharma Report re Different Salts of Azelastine: Solubility and Partition Coefficients (AZ0001642 – AZ0001645)			402, F, H
473		Report re Azelastine (AZ0001649 – AZ0001667)			402, F, H
474	01/26/1990	Asta Pharma Report re Azelastine Eye Drops (AZ0001668 – AZ0001684)			402, F, H
475	05/25/1990	Memorandum re Azelastine HCL (AZ0001685 – AZ0001693)			402, F, H
476	02/09/1990	Asta Pharma Report re Study on Sensitizing Capacity of IC-5505 (AZ0001704 – AZ0001737)			402, F, H
477	09/11/1990	Asta Pharma Report re Protective Effect of Azelastine (AZ0001742 – AZ0001746)			402, F, H
478	03/29/1990	Asta Pharma Report re Azelastine HCL Solution (AZ0001756 – AZ0001818)			402, F, H
479	11/02/1989	Memorandum re Azelastine HCL (AZ0001874 – AZ0001886)			402, F, H

480	*	05/17/1985	Report re Influence of Azelastine, Its Metabolites and Analogs on Aeroallergen-Induced Pulmonary Mechanics Changes in Guinea Pig Asthma Model (AZ0002216 – AZ0002223)			402, F, H
481		12/16/1985	Report re Inhibition of Leukotriene C4 Synthesis By Azelastine and Its Putative Metabolites In Rat Mixed Peritoneal Cells (AZ0002313 – AZ0002327)			402, F, H
482		01/13/1986	Report re Inhibition of Allergic Histamine Release From Rat Peritoneal Mast Cells By Azelastine (AZ0002340 – AZ0002357)			402, F, H
483		04/11/1986	Report re Inhibition of Acute Lung Anaphylactic Responses by Azelastine HCL (AZ0002373 – AZ0002387)			402, F, H
484	*	04/16/1986	Report re Influence of Isomers, Metabolites and Analogs of Azelastine on Antigen-Induced Contractile Responses in Rat Trachea (AZ0002388 – AZ0002422)			402, F, H
485	*	04/30/1986	Report re Antagonism of Histamine by Azelastine (AZ0002423 – AZ0002440)			402, F, H
486		09/03/1986	Report re Effect of Azelastine on Allergic Pulmonary Mechanic Changes in Sensitized Guinea Pigs (AZ0002535 – AZ0002556)			402, F, H
487		09/04/1986	Report re Effect of Azelastine on 5-HETE Formation in Rat Mixed Peritoneal Cells (AZ0002557 – AZ0002574)			402, F, H
488	*	11/19/1986	Report re Effect of Azelastine on IgE-Mediated Passive Cutaneous Anaphylaxis in Rats (AZ0002575 – AZ0002585)			402, F, H
489		11/25/1986	Report re Effect of Azelastine on Phospholipase A2-Induced Airway Hyperactivity in Rat Isolated Tracheal Segments (AZ0002586 – AZ0002613)			402, F, H
490		12/18/1986	Report re Effect of Azelastine on Calcium Ionophore A23187-Stimulated Leukotriene B4 Synthesis in Rat Mixed Peritoneal Cells (AZ0002614 – AZ0002635)			402, F, H
491		12/19/1986	Report re Inhibition of Leukotriene C4 Synthesis by Azelastine (AZ0002636 – AZ0002665)			402, F, H



492	02/02/1987	Report re Effect of Azelastine and Analogs on Carrageenan- and PAF-Induced Rat Paw Edema (AZ0002666 – AZ0002673)			402, F, H
493	04/13/1987	Report re Effect of Newer Metabolites of Azelastine on Antigen-Induced Responses to Cold Provocation (AZ0002718 – AZ0002731)			402, F, H
494	06/18/1987	Report re Effect of Azelastine on Allergic LTC <sub>4</sub> Synthesis in Guinea Pig Chopped Lung (AZ0002732 – AZ0002753)			402, F, H
495	06/15/1988	Report re Inhibition of Leukotriene B <sub>4</sub> Formation by Azelastine (AZ0002782 – AZ0002802)			402, F, H
496	07/15/1988	Report re Comparison of the Inhibitory Activity of Azelastine and Analogs (AZ0002858 – AZ0002871)			402, F, H
497	09/13/1988	Report re Evaluation of Antiasthmatic Activity of Azelastine (AZ0002912 – AZ0002925)			402, F, H
498	09/21/1988	Report re Inhibition of Leukotriene C <sub>4</sub> Formation by Azelastine (AZ0002926 – AZ0002943)			402, F, H
499	12/05/1988	Report re Effect of Newer Metabolites of Azelastine on Allergic Histamine Secretion (AZ0002956 – AZ0002968)			402, F, H
* 500	01/03/1989	Report re Effect of Newer Analogs of Azelastine on Allergic Histamine Secretion (AZ0002969 – AZ0002984)			402, F, H
501	01/03/1989	Report re Antagonism of Ca <sup>2+</sup> -Induced Contractile Responses by Azelastine (AZ0002985 – AZ0002997)			402, F, H
502	01/10/1989	Report re Effect of Azelastine on 5-HETE Formation in Rat Mixed Peritoneal Cells (AZ0002998 – AZ0003014)			402, F, H
503	01/16/1989	Report re Effect of Azelastine on the Gastrointestinal Mucosa In Rats (AZ0003015 – AZ0003024)			402, F, H
503	01/17/1989	Report re Effect of Azelastine on Allergic Responses to Cold in Rat Tracheal In Vitro (AZ0003025 – AZ0003033)			402, F, H
505	01/27/1989	Report re Effect of Azelastine on Phospholipase A <sub>2</sub> -Induced Contractile Responses to Cold in Rat Tracheal Segments (AZ0003034 – AZ0003041)			402, F, H
506	01/30/1989	Report re Effect of Azelastine Analogs on Antigen and Histamine-Induced Cutaneous Responses in Rats (AZ0003042 – AZ0003052)			402, F, H
507	01/31/1989	Report re Effect of Azelastine on the Intestinal Mobility in Rats (AZ0003053 – AZ0003059)			402, F, H



508	05/22/1989	Report re Effect of Azelastine on Tetraethylammonium Induced Airway Hyperactivity to Cooling in Rat Trachea (AZ0003074 – AZ0003088)			402, F, H
509	05/22/1989	Report re Effect of Azelastine on Calcium Ionophore A23187 Stimulated LTb4 Generation (AZ0003089 – AZ0003104)			402, F, H
510	05/23/1989	Report re Effect of Azelastine on 5-HETE Formation on Calcium Ionophore A23187 Stimulated 5-HETE Formation (AZ0003105 – AZ0003120)			402, F, H
511	09/18/1989	Report re Effect of Piperidine and Phenylethyl Analogs on Allergic Histamine Secretion (AZ0003141 – AZ0003153)			402, F, H
512	11/16/1989	Report re Effect of Azelastine on Tracheal Secretion of Phenol Red in Mice (AZ0003200 – AZ0003206)			402, F, H
513	01/30/1990	Report re Effect of Azelastine on Tracheobronchial Secretion of Fluorescein Sodium (AZ0003242 – AZ0003250)			402, F, H
514	05/01/1990	Report re Effect of Newer Backup Compounds of Azelastine of Calcium Ionophore-Stimulated 5-HETE Formation (AZ0003314 – AZ0003326)			402, F, H
515	06/06/1990	Report re Effect of Analogs on Early Asthmatic Responses (AZ0003327 – AZ0003340)			402, F, H
516	06/13/1990	Report re Effect of Azelastine Backups on Allergic Histamine Secretion (AZ0003341 – AZ0003354)			402, F, H
517	08/13/1990	Report re Effect of Azelastine Backup Compounds on Allergic Responses to Cold Provocation (AZ0003355 – AZ0003362)			402, F, H
518	11/12/1990	Report re Effect of Azelastine Backup Compounds on Early Asthmatic Responses (AZ0003397 – AZ0003405)			402, F, H
519	03/21/1991	Report re Effects on Calcium Ionophore-Stimulated LTC4 Formation (AZ0003406 – AZ0003421)			402, F, H
520	03/21/1991	Report re Effects on Calcium Ionophore-Stimulated LTC4 Formation (AZ0003422 – AZ0003437)			402, F, H
521	07/09/1991	Report re Effect of Azelastine on Aeroallergen-Induced Bronchial Eosinophilia (AZ0003468 – AZ0003485)			402, F, H

522	12/04/1986	Report re Ability of Azelastine to Inhibit Formation of Calcium Ionophore A23187 Stimulated Leukotriene B4 (AZ0003948 – AZ0003968)			402, F, H
523	12/19/1986	Report re Inhibition of Leukotriene C4 Synthesis By Azelastine (AZ0003969 – AZ0003998)			402, F, H
524	04/13/1987	Report re Effect of Azelastine Metabolites on Antigen-Induced Responses to Cold Provocation (AZ0003999 – AZ0004012)			402, F, H
525	05/22/1989	Report re Effect of Azelastine on Calcium Ionophore A23187 LTB4 Generation (AZ0004013 – AZ0004015)			402, F, H
526	05/23/1989	Report re Effect of Azelastine on 5-HETE Formation on Calcium Ionophore A23187 Stimulated 5-HETE Formation (AZ0004016 – AZ0004031)			402, F, H
527	04/13/1987	Degussa Report re Comparison of the Effects of Azelastine Following Intravenous Administration of the Ovalbumin-Induced Bronchospasm (AZ0004034 – AZ0004045)			402, F, H
528	06/25/1987	Letter to Dr. Sophia re Inhibitory Potency of Azelastine on H1 Receptors (AZ0004058 – AZ0004059)			402, F, H
529	03/01/1985	Report re Pharmacological Summary of Azelastine (AZ0004131 – AZ0004190)			402, F, H
530	04/03/1992	Report re Azelastine on Aeroallergen-Induced Bronchial Eosinophilia in Guinea Pigs (AZ0004204 – AZ0004227)			402, F, H
531	02/27/1984	Report re Inhibition of Allergic and Nonallergic Histamine Secretion by Azelastine in Rat Peritoneal Mast Cells (AZ0004717 – AZ0004736)			402, F, H
532	08/11/1992	Memorandum re Asta Study No. 888186 (AZ0005166 – AZ0005165)			402, F, H
533	10/19/1992	Memorandum re Azelastine Asta Report: Investigation on the Toxicokinetic Profile of Azelastine (AZ0006423 – AZ0006584)			402, F, H
534		Report re Pharmacokinetics of Azelastine and Metabolite in Guinea Pigs (AZ0006905 – AZ0006908)			402, F, H
535	06/07/1988	Letter to Dr. Sophia re Dr. Diamantis' Presentations (AZ0006930 – AZ0006947)			402, F, H

536	05/12/1988	Letter to Dr. Herbst re Experimental Results re Azelastine (AZ0007084 – AZ0007103)			402, F, H
537	08/04/1989	Letter to Dr. Fricke re Inventory and Assay Results from Dog Plasma Samples (AZ0007728 – AZ0007730)			402, F, H
538	03/21/1989	Letter to Dr. Fricke re Assay and Analysis Results of Dog Plasma Samples (AZ0007751 – AZ0007752)			402, F, H
539	06/05/1987	Handwritten notes and Agenda from Meeting re Azelastine Modes of Action and Implications (AZ0007792 – AZ0007828)			402, F, H
540		Azelastine and Desmethyazastine Suppress Acetylcholine-Induced Contraction and Depolarization in Human Airway Smooth Muscle (AZ0007868 – AZ0007879)			402, F, H
541	10/29/1990	Report re Azelastine and Desmethyazastine Suppress Acetylcholine-Induced Contraction and Depolarization in Human Airway Smooth Muscle (AZ0007988 – AZ0008001)			402, F, H
542	06/27/1991	Report re Effect of Azelastine Backup Compounds on Leukotriene B4 Formation (AZ0008294 – AZ0008312)			402, F, H
543	04/15/1988	Lab Notebook (AZ0008565 – AZ0008622)			402, F, H, 106
544	05/08/1985	Lab Notebook (AZ0008649 – AZ0008788)			402, F, H
545	09/29/1985	Lab Notebook (AZ0008894 – AZ0009068)			402, F, H
546	09/25/1986	Lab Notebook (AZ0009069 – AZ0009239)			402, F, H
547	09/21/1987	Lab Notebook (AZ0009240 – AZ0009383)			402, F, H
548	02/02/1989	Lab Notebook (AZ0009384 – AZ0009492)			402, F, H
549	08/04/1989	Lab Notebook (AZ0009493 – AZ0009602)			402, F, H
550	09/25/1986	Lab Notebook (AZ0009758 – AZ0009813)			402, F, H
551	01/13/1986	Lab Notebook (AZ0009918 – AZ0009940)			402, F, H
552	07/28/1989	Lab Notebook (AZ0010224 – AZ0010270)			402, F, H
553	02/11/1988	Lab Notebook (AZ0010383 – AZ0010469)			402, F, H
554	02/11/1988	Lab Notebook (AZ0010470 – AZ0010567)			402, F, H
555	03/29/1988	Lab Notebook (AZ0011236 – AZ0011275)			402, F, H
556	12/06/1984	Lab Notebook (AZ0011509 – AZ0011728)			402, F, H
557	07/30/1992	Lab Notebook (AZ0011778 – AZ0011914)			402, F, H
558	02/02/1989	Lab Notebook (AZ0011915 – AZ0011993)			402, F, H
559	10/16/1986	Lab Notebook (AZ0011994 – AZ0012100)			402, F, H

560	08/04/1989	Lab Notebook (AZ0012305 – AZ0012489)			402, F, H
561	07/30/1992	Lab Notebook (AZ0012702 – AZ0012744)			402, F, H
562		Lab Notebook (AZ0012745 – AZ0012811)			402, F, H
563	07/02/1992	Lab Notebook (AZ0012812 – AZ0012856)			402, F, H
564	08/19/1991	Lab Notebook (AZ0012857 – AZ0012897)			402, F, H
565	10/27/1986	Memorandum re Meeting with Degussa Pharma Representatives (AZ0013916 – AZ0013978)			402, F, H
566		Test Results (AZ0014000)			402, F, H, 106
567		Test Results re Azelastine Study No. 83H221 (AZ0014379 – AZ0014400)			402, F, H
568	04/28/1989	Report re Pharmacokinetics of Azelastine in Guinea Pig (AZ0015675 – AZ0015764)			402, F, H
569	04/28/1989	Addendums #1 and #2 to Report re Pharmacokinetics of Azelastine in Guinea Pig (AZ0015765 – AZ0015768)			402, F, H
570	09/28/1989	Report re C-Metabolic Profiles in Selected Tissues After A Dose of Azelastine (AZ15877 – AZ0015906)			402, F, H
571	10/20/1989	Report re Disposition of Azelastine in Male Guinea Pigs (AZ0015907 – AZ0015927)			402, F, H
572	09/28/1989	Report re Pharmacokinetics of Azelastine (AZ0015928 – AZ0015994)			402, F, H
573	11/16/1989	Report re Effect of Azelastine on Tracheal Secretion in Mice (AZ0016703 – AZ0016709)			402, F, H
574	04/22/1991	Report re Effect of Azelastine Pamoate Salt on Antigen-, Histamine- and 5-HT- Induced Cutaneous Responses in Rats (AZ0016710 – AZ0016719)			402, F, H
575	10/01/1990	Report re Effect of Azelastine Backups on TEA-Induced Airway Hyper-responsiveness (AZ0016720 – AZ0016733)			402, F, H
576	02/12/1990	Report re Effect of Azelastine Backups on Calcium Ionophore Secretion (AZ0016734 – AZ0016745)			402, F, H
577	02/26/1990	Report re Effect of Azelastine on Tetraethylammonium-Induced Airway Hyper-reactivity (AZ0016746 – AZ0016759)			402, F, H
578	11/16/1989	Report re Effect of Azelastine on Tracheal Secretion of Phenol Red in Mice (AZ0016760 – AZ0016766)			402, F, H
579	11/27/1989	Report re Summary of the Pharmacologic Activity of W-3006M (AZ0016767 – AZ0016791)			402, F, H

580	04/21/1989	Report re Three Month Oral Toxicity Study of Azelastine (AZ16812 – AZ0016937)			402, F, H
581	10/17/1989	Report re Determination of Azelastine in Rabbit Plasma (AZ0017109 – AZ0017139)			402, F, H
582	09/06/1988	Report re Segment II Study of an Azelastine Stimulated Release in Rabbits (AZ0017143 – AZ0017226)			402, F, H
583	08/26/1988	Report re Determination of Azelastine in Rabbit Plasma (AZ0017231 – AZ0017277)			402, F, H
584		Test Results re Azelastine (AZ0017387 – AZ0017463)			402, F, H
585	02/19/1992	Report re Plasma Levels of Azelastine In Mice (AZ0018315 – AZ0018320)			402, F, H
586	02/26/1992	Letter to Dr. Sophia and Protocol Drafts of Azelastine Toxicity Study (AZ0018340 – AZ0018364)			402, F, H
587		Draft Study Protocol: Investigation on the Pharmacokinetics of Azelastine in the Mouse (AZ0018368 – AZ0018381)			402, F, H
588	06/23/1989	Report re Six-Month Intranasal Toxicity Study (AZ0018424 – AZ0018434)			402, F, H
589	12/21/1981	Azelastine Testing Conception (AZ0018959 – AZ0018984)			402, F, H
590	01/18/1982	Letter to Dr. Perhach and Synopsis of Pharmacological, Toxicological and Clinical Findings with Azelastine (AZ0019008 – AZ0019042)			402, F, H
591	11/02/1983	Allergic Properties of Azelastine Hydrochloride and its Main Metabolite 6-Hydroazelastine Studies In Vitro by Y. Sakuma (Ibaragi 300-26, Japan) (AZ19113 – AZ0019115)			402, F, H
592	05/18/1983	Studies on the Metabolism of 14 C-A-5610 x HCL in Rats (AZ0019162 – AZ0019183)			402, F, H
593		Physical Sample: CromoHEXAL Nasenspray			402, F, H
593A		Product Insert for: CromoHEXAL Nasenspray			402, F, H
594		Physical Sample: Ratiopharm Heuschnupfen-spray			402, F, H
594A		Product Insert for: Ratiopharm Heuschnupfen-spray			402, F, H
595		Physical Sample: Livocab Nasenspray			402, F, H
595A		Product Insert for: Livocab Nasenspray			402, F, H
596		Physical Sample: Livocab (Beclometason 0.05%) Nasenspray			402, F, H



596A			Product Insert for: Livocab (Beclometasone 0.05%) Nasenspray			402, F, H
597			Physical Sample: Bausch & Lomb Vividrin akut Nasenspray			402, F, H
597A			Product Insert for: Bausch & Lomb Vividrin akut Nasenspray			402, F, H
598			Physical Sample: Bausch & Lomb Vividrin Nasenspray			402, F, H
598A			Product Insert for: Bausch & Lomb Vividrin Nasenspray			402, F, H
599	11/19/63		German Patent: 1208036 (OPT-MEDA000127 – OPT-MEDA000128)			402
600			Product Insert for Vividrin (OPT-MEDA000280)			402, F, H, X
601	02/17/95		Meeting minute notes with handwritten notes (OPT-MEDA000467)			402, F, H, X
602	09/06/85		Memo from Dr. Aurch to Dr. Breuel re: Azelastin-Nasenspray (OPT-MEDA000557 – OPT-MEDA558)			402, F, H
603	06/16/87		Summary Report of Clinical Trial (OPT-MEDA000579 – OPT-MEDA000583)			402, F, H, X
604	03/05/87		Summary Report of Clinical Trial (OPT-MEDA000584 – OPT-MEDA000588)			402, F, H, X
605	02/20/87		Summary Report of Clinical Trial (OPT-MEDA000589 – OPT-MEDA000596)			402, F, H, X
606			German Article (OPT-MEDA0006000 – OPT-MEDA000615)			402, F, H, 106
607	05/31/88		Memo from Dr. Herbst to Dr. Hettche (OPT-MEDA001268)			402, F, H
608	05/25/88		Memo from Dr. Hettche to Dr. Engel (OPT-MEDA001269)			402, F, H
609	10/28/89		Asta Pharma Report: Report on Anti-allergic Formulations Administered By Conjunctival Topical Route (OPTI00000199 – OPTI0000213)			402, F, H, X
610	06/15/88		Asta Pharma Report: Ocular antihistaminic activity in rabbit (OPTI0000218 – OPTI0000232)			402, F, H, X

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EXHIBIT ALSO APPEARS ON PLAINTIFF'S EXHIBIT LIST

611	06/15/88	Asta Pharma Report: Comparative ocular antihistaminic activity (OPTI0000241 – OPTI0000253)			402, F, H, X
612	02/09/90	Asta Pharma Report: Study on the sensitizing capacity of LC-5505 by ocular application (OPTI0000262 – OPTI0000296)			402, F, H, X
613	04/25/88	Asta Pharma Report: Examination of the Surface Anaesthetic Action of Azelastine-HCL on the Cornea of the Albino Rabbit (OPTI0000301 – OPTI0000314)			402, F, H, X
614	04/21/88	Asta Pharma Report: LC-5505: Determination of its anaesthetic activity. Comparison with benoxinate and atazolone (OPTI0000316 – OPTI0000329)			402, F, H, X
615	04/21/88	Asta Pharma Report: LC55-05: Determination of its anaesthetic activity. Comparison with benoxinate and atazolone (OPTI0000348 – OPTI0000361)			402, F, H, X
616		Asta Pharma Report: Study of the effect of LC-5505 at 0.1% on the corneal reepithelialization process in rabbits (OPTI0000367 – OPTI0000378)			402, F, H, X
617	01/22/81	Degussa Report: The Study of Azelastine in Aqueous Solution for Irritating Effects on the Mucous Membrane Following Single Application to the Eye of the Rabbit (OPTI0000597 – OPTI0000613)			402, F, H, X
618	02/24/86	Degussa Report: Azelastine 0.2% Nasal Spray. Testing the mucous membrane irritancy after repeated application to the rabbit eye for 5 days (OPTI0000615 – OPTI0000650)			402, F, H, X
619	05/06/87	Degussa Report: Testing the mucous membrane irritancy after repeated application to the rabbit eye for 5 days (OPTI0000652 – OPTI0000698)			402, F, H, X
620	02/26/86	Asta Pharma Report: Compared acute ocular tolerance (OPTI0001165 – OPTI0001173)			402, F, H, X
621	02/11/87	Asta Pharma Report: Compared acute ocular tolerance (OPTI0001179 - OPTI0001188)			402, F, H, X



622	04/25/88	Asta Pharma Report: Examination of the Surface Anaesthetic Action of Azelastine-HCL on the Cornea of the Albino Rabbit (OPTI0001265 – OPTI0001278)			402, F, H, X
623	01/23/99	Azelastine Eye Drops. IND #54,893 Asta Medica, Inc. Annual Progress Report (OPTI0002147 – OPTI0002182)			402, F, H, X
624	05/12/00	Asta Pharma Report: Clinical trial to assess efficacy and safety of azelastine eye drops in patients with perennial allergic conjunctivitis/rhinoconjunctivitis (OPTI0002598 – OPTI0002927)			402, F, H, X
625		Azelastine Eye Drops-Pre IND Meeting: Introduction and Rationale for US Clinical Program Summary of European Clinical Studies (OPTI0004107 – OPTI0004112)			402, F, H, X
626	1988	A. Aabbah and M. Marzetto; "Azelastine Eye Drops in the Treatment of Seasonal Allergic Conjunctivitis or Rhinoconjunctivitis in Young Children", reprinted from Current Medical Research and Opinion Vol. 14 No. 5 1988 (OPTN0000422 – OPTN0000431)			402, F, H, X
627		Zaditor Product Monograph (OPTN0000458 – OPTN0000473)			402, F, H, X
628	09/08/00	Letter from W. Rumble to I. Army re: response to Ast Medica's 08/25/00 submission (OPTN0001644 – OPTN0001647)			402, F, H, X
629		Optivar product insert (OPTN0001714 – OPTN0001715)			402, F, X
630		Application Summary (OPTN0002073 – OPTN0002241)			402, F, H, X, 1006
631		Official Hague Convention Documents relating to the testimony of Dr. Jurgen Engel, Including Letters of Requests and Official Transcripts from the German Court (including exhibits)			402, F, H
631A		Request for Judicial Assistance with German Translation			402
631B		Questionnaire for Dr. Jurgen Engel with German translation			402

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EXHIBIT ALSO APPEARS ON PLAINTIFF'S EXHIBIT LIST

631C		List of exhibits for Dr. Jurgen Engel with German translation			402
631D		United States Patent: 5,164,194 with German translation (Engel 1)			NONE
631E		United States Patent: 4,704,387 with German translation (Engel 2)			402
631F	03/27/86	German Patent: DE 3530793 A1 (MPAT0246 – MPAT0272) (Engel 3)			402
631G		Engel 4			402
631H	09/30/85	Memo from Dr. Hettche to Dr. Aurich re: Azelastin-Nasenspray (AS-MEDA0009924) (Engel 5)			402, F, H
631I	07/27/72	German Patent: 2164058 (MPAT0209 – MPAT0245) (Engel 6)			402
631J	02/16/87	Tuckerman Declaration with translation (Engel 7)			NONE
631K	01/23/90	Szelenyi Declaration with translation (MP0063 – MP0064) (MP0062) (Engel 8)			NONE
631L		Article from Aerosols in Medicine (Engel 9)			402, F, H
631M		VADE-MECUM for Pharmacist 12 <sup>th</sup> revised edition (AS-MEA0000624- AS-MEDA0000629) (Engel 10)			402, F, H
631N	09/13/88	ASTA Pharma report: Development pharmaceuticals of Azelastine Hydrochloride 0.1% Nasal Spray with translation (AS- MEDA0003522-AS- MEDA0003525) (Engel 11)			402, F, H
631O	05/30/07	Deposition of Jurgen Engel with translation			402, F, H
632		Number not used			N/A
633		Official Hague Convention Documents relating to the testimony of I. Szelenyi, Including Letters of Requests and Official Transcripts from the German Court (including exhibits			
633A		Request for Judicial Assistance with German Translation			402, H
633B		Questionnaire for Dr. Istvan Szelenyi with German translation			402
633C		List of exhibits for Dr. Istvan Szelenyi with German translation			402
633D	11/17/92	United States Patent: 5,164,194 with German translation (Szelenyi 1)			NONE

633E	01/23/90	Szelenyi Declaration (MP0063 – MP0064) (Szelenyi 2) United States Patent: 4,704,387 with German translation (Szelenyi 3)		NONE
633F	11/03/87			402
633G	06/01/90	Szelenyi Declaration (MP0069 – MP0070) (Szelenyi 4)		NONE
633H	09/20/07	Deposition of Istvan Szelenyi with translation		402, H
634		Official Hague Convention Documents relating to the testimony of H. Hettche, including Letters of Requests and Official Transcripts from the German Court (including exhibits		402, F, H
634A	05/30/07	Request For Judicial assistance with German translation		402
634B		Questionnaire for Helmut Hettche with German translation		402
634C		List of Exhibits Helmut Hettche with German translation		402
634D		German Patent Application 268772 (with English translation) (Hettche 1)		402
634E	11/17/92	Unites States Patent: 5,164,194 with German translation (Hettche 2)		NONE
634F	10/27/88	European Patent Application 0 316 633 B1 (Original & English translation) (Hettche 3)		402, F, H
634G	03/08/96	Decision about the Revocation of the European Patent (Article 101(1) of the EPC) (Original and English translation) (MPAT0000395 – MPAT0000421) (Hettche 4)		402, F, H
634H	04/05/00	Decision of the Technical Court of Appeals 3.3.2 of April 5, 2000 (Original and English translation) (MPAT0000245 – MPAT0000265) (Hettche 5)		402, F, H
634I		German Patent 21 64 058 (with English translation) (MP0209 – MP0245) 9Hettche 6)		402
634J	05/28/74	United States Patent: 3,813,384 with German translation (Hettche 7)		402, F, H
634K		N. Brock, D. Lenke H. Abel, "Expose on the Pharmacology and Toxicology of the Antihistamine Preparation ASTA A 5610, " From the Pharmacology Department of Asta-Werke AG, Chemische Fabrik, Brackwede/Westf (AT100001098 – AT100001105)		402, F, H
634L		Original & German translation) (Hettche 8) Sofia Abstract with German translation (Hettche 9)		402, F, H

634M		(AS-MEDA0001568) (Hettche 10)			402, 106
634N	9/6/85	Degussa document (AS- MEDA0000601- AS-MEDA0000602) (Hettche 11)			402, F, H
634O	01/27/86	Memo from Dr. Hettche to Dr. Herbsrt re: Azelastin nasal spray (AS-MEDA0004168 – AS-MEDA0004169) (Original and translation) Hettche 12)			402, F, H
634P	08/13/90	Memo from Dr. Hettche to Dr. Herbst (AS-MEDA0001345) Hettche 13			402, F, H
634Q	02/18/06	Handwritten Notes (Hettche 14)			402, F, H
634R	8/12/87	AS-MEDA0000600 (Hettche 15)			402, F, H
634S	11/03/87	Unites States Patent: 4,704,387 with German translation (Hettche 16)			402
634T	09/17/86	German Patent Application 928458, (Original and translation) (A05457 – A05505) (Hettche 17)			402
634U	08/22/85	German Patent Application 34 8 776.8 (Hettche 18)			402, F, H
634V		VADE-MECUM for Pharmacist 12 <sup>th</sup> revised edition (AS-MEDA0000624- AS-MEDA0000629) (Hettche 19)			402, F, H
634W	00/00/71	H. Breuninger, "Nasentropfen, Ohrentropfen," ["Nasal Drops, ear drops"], HNO, Vol. 19, Issue 3, pp. 65-68 (March 1971)(A06107-A06110) (Hettche 20)			402, F, H
634X		Scheduling status document (A06012 – A-06015) (Hettche 21)			402, F, H
634Y	00/00/78	H. Sucker, P. Fuchs, P. Speiser, Pharmazeutische Technologie (AS-MEDA0007754 – AS-MEDA0007755) (Original & translation) (Hettche 22)			402, F, H
634Z	00/00/81	H.J.M. van de Donk, J. Zuidema and F.W.H.M. Merkus, "The effects of nasal drops on the ciliary beat frequency of chicken embryo tracheas," Rhinology, Vol. 19, pp. 215-230 (1981)(Hettche 23).			F
634AA		Article in foreign language entitled, "Allergie gegen topische Antihistaminika - Diskrepanz zwischen Literatur und Praxis" (A05987 - A05989) (Hettche 24)			402, F, H
634BB	09/13/88	ASTA Pharma report: Development pharmaceuticals of Azelastine Hydrochloride 0.1% Nasal Spray (AS-MEDA0003522-AS- MEDA0003525) Hettche 25			402, F, H

634CC	01/23/90	Szelenyi Declaration with German Translation (MPAT0063 – MPAT0064 (Hettche 26)			NONE
634DD		Excerpt from File History with English translation (MP0062) (Hettche 27)			106
634EE	06/01/90	Szelenyi Declaration with German translation (MP0069 – MP0070)(Hettche 28)			NONE
634FF	12/04/07	Deposition transcript of Helmut Hettche with translation			402, H
635	03/24/72	Abstract from Science Vol. 75: Cilia: Activation Coupled to Mechanical Stimulation by Calcium Influx			402, F, H
636	1983	Application Pharmacology: Pharmacometrics Vol. 26 No. 2			402, F, H
637	1986	N. Bonini, M. Gustin, D. Nelson; "Regulation of Ciliary Motility by Membrane Potential in Paramecium: A Role for Cyclic AMP, Cell Motility and Cytoskeleton 6:256-272 (1986)			402, F, H
638	1985	T. Hennessey, "Injected cyclic AMP increases ciliary beat frequency in conjunction with membrane hyperpolarization, European Journal of Cell Biology 36, 153-156 (1985)			
639	1992	K. Thomas, S. Ollier, H. Ferguson, R. Davies; "The effect of intranasal azelastine, Rhinolast, on nasal airways obstructions and sneezing following provocation testing with histamine and allergen; Clinical Experimental Allergy, 1992 Volume 22 pages 642-647			402, F, H

# **EXHIBIT 17**

## EXHIBIT 17

**DEFENDANTS' OBJECTIONS TO PLAINTIFF'S LIST OF TRIAL EXHIBITS**

Attached are Defendants' objections to Plaintiff's list of trial exhibits, except as to the accuracy of translations.

Defendants reserve the right to make additional objections to any exhibit, including objections as to foundation, depending on the witness through which the Plaintiff may seek to introduce the exhibit.

Generally, Defendants have adopted the same abbreviations used for Plaintiff's objections to Defendants' list of trial exhibits with one addition:

<b>102</b>	FRE 102 (Cumulative/duplicative)
<b>106</b>	FRE 106 (Incomplete)
<b>402</b>	FRE 402 (Relevance)
<b>403</b>	FRE 403 (Prejudicial)
<b>408</b>	FRE 408 (Settlement/compromise)
<b>1006</b>	FRE 1006 (Improper summary of voluminous records)
<b>32</b>	Fed. R. Civ. P. 32
<b>F</b>	Foundation (includes FRE 901)
<b>H</b>	Hearsay (includes FRE 802)
<b>C</b>	Confidential - requires sealed courtroom for introduction



**MedPointe Healthcare, Inc. v. Apotex, Inc., et al.**  
 Civil Action No. 1:2006-cv-00164  
 Plaintiffs Trial Exhibits

PTX	Description	Bates Range	PDX	Admission		Date Admitted
				No Obj.	Objection Basis	
1	Certified Copy of US Patent No. 5,164,194					
2	Prosecution History for US Patent No. 5,164,194	MPAT 7-186				
3	2007-04-13 Deposition of Corey Fishman				FRCP 32, FRE 802	
4	2007-04-18 Deposition of Naresh Chand				FRCP 32, FRE 802	
5	2007-04-26 Deposition of Wan Jiang				FRE 402, 403	
6	2007-04-26 Deposition of Suganya Ramachandra				FRE 402, 403	
7	2007-04-27 Deposition of Jeff Michaud				FRE 402, 403	
8	2007-05-16 Deposition of Cihua Yang				FRE 402, 403	
9	2007-05-16 Deposition of Scott Deng				FRE 402, 403	
10	2007-05-17 Deposition of Muhammad Hassan				FRE 402, 403	
11	2007-05-17 Deposition of Xue Ming Zhang				FRE 402, 403	
12	2007-05-18 Deposition of Gina Louise Siranni				FRE 402, 403	
13	2007-06-14 Deposition of R. Duane Sofia				FRCP 32	
14	2007-06-21 Deposition of Ellen Gettenberg				FRE 402, 403	
15	2007-07-03 Deposition of Richard Spivey				FRCP 32	
16	2007-07-09 Deposition of Harry Sacks				FRE 402, 403	
17	2007-07-09 Deposition of Elizabeth French				FRE 402, 403	
18	2007-08-01 Deposition of Jeffrey Hostler				FRCP 32, FRE 802	
19	2007-10-10 Deposition of Maureen Donovan				FRCP 32, FRE 802	
20	2007-10-12 Deposition of Stephen Byrn				FRCP 32, FRE 802	
21	2007-10-16 Deposition of Eli Meltzer				FRCP 32, FRE 802	
22	2007-10-17 Deposition of Howard Schwartz				FRCP 32, FRE 802	
23	2007-10-19 Deposition of Richard Dalby				FRCP 32, FRE 802	
24	2007-10-24 Deposition of Robert Langer				FRCP 32, FRE 802	
25	2008-01-04 Deposition of Robert Langer				FRCP 32, FRE 802	
26	N. Chand, "Inhibition of Allergic and Nonallergic Histamine Secretion by Azelastine, Its Putative Metabolites and Analogs in Rat Peritoneal Mast Cells and Rabbit Mixed Leukocytes (Basophils)," Wallace Laboratories, Pharmacology, PH-84-6, February 27, 1984 (Plaintiff's Deposition Exhibit 1).	ASN 3646-3665	1		FRE 802	
27	Report No. PH-86-2	ASN 3727-3744	2		FRE 802	
28	Notice of Deposition: Docket No. 66		3		FRE 402, 403	
29	Drug Master File: Azelastine Hydrochloride-Daito	A 4986-5050	4		FRE 402, 403	
30	Azelastine Hydrochloride 137 mcg/mL: Quality Overall Summary	A 1023-1052	5		FRE 402, 403, 802	

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31	Lab Notebook pages (Book No. 12040048)	A 2543-2550	6		FRE 402, 403	
32	Lab Notebook pages (Book No. 12040113)	A 2632-2677	7		FRE 402, 403	
33	Lab Notebook pages (Book No. 12040102)	A 2472-2517	8		FRE 402, 403	
34	Lab Notebook pages (Book No. 12050016)	A 2422-2435	9		FRE 402, 403	
35	Lab Notebook pages (Book No. 12050016)	A 2384-2421	10		FRE 402, 403	
36	Lab Notebook pages (Book No. 12050065)	A 2342-2347	11		FRE 402, 403	
37	Lab Notebook pages (Book No. 10050006)	A 4243-4255	12		FRE 402, 403	
38	Lab Notebook pages (Book No. 10050006)	A 3311-3314	13		FRE 402, 403	
39	Lab Notebook pages (Book No. 10050006)	A 4501-4530	14		FRE 402, 403	
40	Lab Notebook pages (Book No. 10050054)	A 4548-4556	15		FRE 402, 403	
41	Lab Notebook pages (Book No. 10050054)	A 4673-4690	16		FRE 402, 403	
42	Test Methods	A 1990-2071	17		FRE 402, 403	
43	Validation Summary of Test Method # AZEL-NASO-10-RH For Assay Per Spray of Azelastine Hydrochloride Nasal Spray	A 2245-2282	18		FRE 402, 403	
44	Labeling Text Draft	AS 956-967	19			
45	Pharmaceutical Development, Book No. 10040031	A 4866-4878	20		FRE 402, 403	
46	Laboratory Notebook, Book No. 10050036	A 4704-4838	21		FRE 402, 403	
47	Laboratory Notebook, Book No. 10050036	A 4324-4449	22		FRE 402, 403	
48	Pharmaceutical Development, Book No. 10050012	A 4879-4919	23		FRE 402, 403	
49	Pharmaceutical Development, Book No. 10050012	A 4531-4547	24		FRE 402, 403	
50	Laboratory Notebook, Book No. 10050036	A 4697-4703	25		FRE 402, 403	
51	Labeling Text Draft	A 968-980	27			
52	Azelastine Hydrochloride Nasal Spray 137mcg: Manufacture	A 1109	28			
53	Formulation Development Department: Product Development Report	A 1099-1107	29			
54	Raw Material Specification and Certificate of Analysis	A 1705-1707	30			
55	Pharmaceutical Development, Book No. 10040015	A 3766-3782	31		FRE 402, 403	
56	Pharmaceutical Development, Book No. 10040012	A 3963-4054	32		FRE 402, 403	
57	Research and Development (RH)	A 5199-5216	34		FRE 402, 403	
58	Apotex Incorporated	A 5217-5234	35		FRE 402, 403	
59	RDD-Product Development, Liquids RH	A 5175-5198	36		FRE 402, 403	
60	Astelin Product Insert		37		FRE 402, 403	
61	Pharmaceutical Development, Book No. 10040045	A 3688-3707	38		FRE 402, 403	
62	Pharmaceutical Development, Book No. 10040074	A 3708-3709	39		FRE 402, 403	
63	Pharmaceutical Development, Book No. 10040074	A 3755-3765	40		FRE 402, 403	

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PTX	Description	Bates Range	PDX	Admission		Date Admitted
				No Obj.	Objection Basis	
64	Pharmaceutical Development, Book No. 10040074	A 3783-3796	41		FRE 402, 403	
65	Pharmaceutical Development, Book No. 10040074	A 3810-3813	42		FRE 402, 403	
66	Pharmaceutical Development, Book No. 10040074	A 3814-3819	43		FRE 402, 403	
67	Pharmaceutical Development, Book No. 10040074	A 3820-3822	44		FRE 402, 403	
68	Pharmaceutical Development, Book No. 10040074	A 3823-3826	45		FRE 402, 403	
69	Pharmaceutical Development, Book No. 10040074	A 3831-3840	46		FRE 402, 403	
70	Pharmaceutical Development, Book No. 10040093	A 3945-3951	47		FRE 402, 403	
71	Pharmaceutical Development, Book No. 10040074	A 3797-3809	48		FRE 402, 403	
72	Pharmaceutical Development, Book No. 10040025	A 4230-4233	49		FRE 402, 403	
73	Pharmaceutical Development, Book No. 10050045	A 4317-4323	50		FRE 402, 403	
74	Azelastine Hydrochloride Nasal Spray 137mcg: Components of the Drug Product (Excipients)	A 1064	51		FRE 402, 403	
75	Azelastine Hydrochloride Nasal Spray 137mcg: Comparison of Generic Drug and Reference Listed Drug	A 948	52		FRE 402, 403	
76	Email to Yasmin Sethna et al. from Anita Hui - February 25, 2005	A 5264	53		FRE 402, 403	
77	Fax to Kaidesh Shnoff from Angela Payne - July 3, 2006	A 5063-5065	54		FRE 402, 403	
78	Email to Tammy McIntire et al. from Bob Billings - July 7, 2004	A 5235	55		FRE 402, 403	
79	Email to Doria Jordanou et al. from Kami-Sue Foo Loi - September 26, 2005	A 5236-5237	56		FRE 402, 403	
80	E-mail to Barry Sherman from Gina Siranani - January 24, 2006	A 5071	58			
81	CNA2 Azelastine HCl log	A 5048-5050	59		FRE 402, 403	
82	Azelastine 137mcg Nasal Spray Info	A 4944	60		FRE 402, 403	
83	Azelastine Nasal Spray International Product Target Charts	A 4945-4946	62		FRE 402, 403	
84	Exec Summary - Azelastine Nasal Spray - F to F Forec	A 5051-5059	63		FRE 402, 403	
85	Levocabasone HCl Product Data	A 894	64		FRE 402, 403	
86	Clemastine	A 890-893	65		FRE 402, 403	
87	Paragraph IV Certification Statement	A 1016	66			
88	Notice of Deposition: Docket No. 67		67		FRE 402, 403	
89	First pages of ANDA	A 942-944	68			
90	Letter of authorization for agent	A 1023	69			
91	Azelastine Hydrochloride Nasal Spray 137mcg: Listed Drug Labeling	A 989-1000	70			
92	Receipt of ANDA		71			
93	Paragraph IV Certification - US Patent 5,164,194	A 5060-5062	72			

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PTX	Description	Bates Range	PDX	Admission		Date Admitted
				No Obj.	Objection Basis	
94	PST Meeting Minutes - July 7, 2004	A 6185-6206	73		FRE 402, 403	
95	PST Meeting Slideshow; Pre-PST Meeting Agenda; Newport Global Horizon website printout	A 6208-6219	74		FRE 402, 403	
96	Donovan Expert Report		77		FRE 802	
97	Byrn Expert Report		78		FRE 802	
98	Kimura, "Effects of Chemical Agents on Ciliated Tracheal Epithelium"	AS-MEDA 430-442	79		FRE 402, 403, 802	
99	Fukuda, "Influence of 1-(2-Ethoxyethyl)-2-(4-methyl-(homopiperazinyl)benzimidazole Difumarate (KB 2413), a New Antiallergic, on Ciliary Movement"	AS-MEDA 10111-10113	80		FRE 402, 403, 802	
100	van de Donk, "The Effects of Drugs on Ciliary Motility"	MPAT 523-531	81		FRE 402, 403, 802	
101	Hermens, "The Influence of Drugs on Nasal Ciliary Movement"	A 574-578	82		FRE 402, 403, 802	
102	Donovan, "Drug Effects on in vivo nasal clearance in rats"		83		FRE 402, 403, 802	
103	U.S. Patent No. 3,813,384	A 133-138	84			
104	U.S. Patent No. 4,704,387	A 564-569	85			
105	Vademecum, for Pharmacists	AS-MEDA 624-629	86		FRE 402, 403, 802	
106	Gundrum, "Experimental Investigations on Action of Antihistaminic Nasal Solutions"		87		FRE 402, 403, 802	
107	Schwartz Expert Report		90		FRE 402, 403, 802	
108	Schwartz Curriculum Vitae		91		FRE 402, 403, 802	
109	Prosecution History for US Patent No. 4,704,387	A 5693-5787	93		FRE 802	
110	Secher, "Significance of H1 and H2 receptors in the human nose: rationale for topical use of combined antihistamine preparations"		94		FRE 802	
111	Remington's Pharmaceutical Sciences (pp. 1124-1132, 1633, 1646, 1662)		95		FRE 106	
112	Schwartz, "The Efficacy and Safety of Nedocromil Sodium 1% Nasal Solution in the Treatment of Ragweed Seasonal Allergic Rhinitis"		96		FRE 402, 403, 802	
113	Schwartz, "Cromolyn Sodium and Its Effects on Nasal Disease"		97		FRE 402, 403, 802	
114	Corren, "Effectiveness of Azelastine Nasal Spray Compared with Oral Cetirizine in Patients with Seasonal Allergic Rhinitis"		98		FRE 402, 403, 802	



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PTX	Description	Bates Range	PDX	Admission		Date Admitted
				No Obj.	Objection Basis	
115	Kirkegaard, "Inhibition of Histamine-Induced Nasal Symptoms by the H1 Antihistamine Chlorpheniramine Maleate"	A 386-395	99			
116	U.S. Pharmacopeia (p. 1655)	AS-MEDA 2129	100		FRE 402, 403	
117	Allergy: Principles and Practice, Third Edition (pp. 1269-1283)		102		FRE 402, 403, 802	
118	Schwartz, "A Multicentered trial of nedocromil sodium, 1% nasal solution, compared with cromolyn sodium and placebo in ragweed seasonal allergic rhinitis"		103		FRE 402, 403, 802	
119	Busse, "New directions and dimensions in the treatment of allergic rhinitis"		104		FRE 402, 403, 802	
120	Electronic Orange Book Query re Diphenhydramine		105		FRE 402, 403	
121	Kirkegaard, "Effect of the H1 Antihistamine Chlorpheniramine Maleate on Histamine-Induced Symptoms in the Human Conjunctiva"	A 366-371	107		FRE 402, 403, 802	
122	Zechei, "Pharmacological and Toxicological Properties of Azelastine, a Novel Antiallergic Agent"	A 5102-5111	109			
123	Chand, "Inhibition of acute lung anaphylaxis by aerosolized azelastine in guinea pigs sensitized by three different procedures"		112			
124	Kemp, "A dose-response study of the bronchodilator action of azelastine in asthma"	A 4951-4957	113			
125	Pecoud, "Effect of a new selective H1 receptor antagonist (Levocabastine) in a nasal and conjunctival provocation test"	A 482-486	114			
126	Lee, "Meta-analysis of Azelastine Nasal Spray for the Treatment of Allergic Rhinitis"	ASC 231-238	115		FRE 402, 403, 802	
127	Pornoy, "Evidence Based Strategies for Treatment of Allergic Rhinitis"		116		FRE 402, 403, 802	
128	Rainer, "Randomized double-blind trial of azelastine nasal spray plus fluticasone nasal spray compared to either agent alone in patients with allergy to Texas Mountain Cedar" (Abstract)		117		FRE 402, 403, 802	
129	Schwartz Revised Expert Rebuttal Report		118		FRE 802	
130	Langer Expert Report		120		FRE 802	
131	Langer Supplemental Expert Report		121		FRE 802	
132	U.S. Patent No 4,767,402		123		FRE 402, 403	
133	Langer, "New Methods of Drug Delivery"		124		FRE 402, 403, 802	

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PTX	Description	Bates Range	PDX	Admission No Obj.	Objection Basis	Date Admitted
134	Langer, "Drug Delivery Modalities" (Chapter of Principles of Pharmacology)		125		FRE 402, 403, 802	
135	U.S. Patent No. 6,060,082		126		FRE 402, 403, 802	
136	German Patent No. 21 64 058		133		FRE 402, 403	
136A	English Translation of German Patent No. 21 64 058				FRE 402, 403	
137	Ansel, "Introduction to Pharmaceutical Dosage Forms" (pp. 246-286)		137		FRE 402, 403	
138	U.S. Patent No. 4,841,047.				FRE 402, 403	
139	Byrn Opposition Expert Report	A 000735-000753	138		FRE 802	
140	Dalby Expert Report				FRE 802	
141	Dalby Opposition Expert Report				FRE 802	
142	Meltzer Expert Report				FRE 802	
143	Meltzer Opposition Expert Report				FRE 802	
144	Schwartz Rebuttal Expert Report				FRE 802	
145	Curriculum Vitae of Dr. Stephen R. Byrn					
146	Remington's Pharmaceutical Sciences, 17th Edition. Ed. Gennaro. Easton: Mack Publishing Company, 1985. 82-83, 1278, 1418-19, 1494.					
147	Apotex's Responses to Plaintiff's First Set of Requests for Admission					
148	The United States Pharmacopeia, 16th Edition. Rockville: United States Pharmacopeial Convention, 1985. 10.					
149	The Merck Index, 14th Edition. Ed. O'Neil. Whitehouse Station: Merck Research Laboratories, 2006. 153.				FRE 402, 403	
150	Hawley's Condensed Chemical Dictionary, 12th Edition. Ed. Lewis. New York: Van Nostrand Reinhold Company, 1993. 354.				FRE 402, 403	
151	McGraw-Hill Dictionary of Chemical Terms. Ed. Parker. New York: McGraw-Hill, 1985. 44.				FRE 402, 403	
152	Chart Illustrating Infringement - Byrn Report Exhibit				FRE 802	
153	List of Previous Expert Testimony				FRE 402, 403, 802	
154	List of Documents Reviewed by Stephen R. Byrn				FRE 802	
155	Results of Phase I Study of E-0659	ATI 002091-002102			FRE 802	

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PTX	Description	Bates Range	PDX	Admission		Date Admitted
				No Obj.	Objection Basis	
156	Ollier, S. "The Effect of Single and Multiple Dose Therapy with Azelastine on the Immediate Asthmatic Response to Allergen Provocation Testing." J. Allergy Clin. Immunology. Vol 78, 1986: 358-64.	A 006422-006428			FRE 802	
157	Remington's Pharmaceutical Sciences, 17th Edition. Ed. Gennaro. Easton: Mack Publishing Company, 1985. 63, 441, 1417, 1492-1517, 1607-1608, 1631, 1633, 1644-61.				FRE 402, 403	
158	H.J.M. van de Donk, J. Zuidema and F.W.H.M. Merkus, "The effects of nasal drops on the ciliary beat frequency of chicken embryo tracheas," Rhinology, Vol. 19, 1981: 215-230.	A 000309-000324			FRE 402, 403	
159	Black, M.J. "Rhinitis Medicamentosa." CMA Journal. Vol. 122, 1980: 881-84.				FRE 402, 403	
160	Gorenberg, D. "Rhinitis Medicamentosa." The Western Journal of Medicine. Vol. 131, 1979: 313-14.				FRE 402, 403	
161	Management of the Allergic Patient: A Text for the Primary Care Physician. Ed. Lieberman, Crawford. New York: Appleton-Century-Crofts, 1982. 155-68.				FRE 402, 403	
162	Johnson, S.R. "Recent Progress in the Computational Prediction of Aqueous Solubility and Absorption." The AAPS Journal. Vol. 8, 2006: E27-E40.				FRE 402, 403	
163	Berge, S.M. "Pharmaceutical Salts." Journal of Pharmaceutical Sciences. Vol. 66, 1977: 1-19.				FRE 402, 403	
164	K. Tasaka and M. Akagi, "Anti-allergic Properties of a New Histamine Antagonist, 4-(p-Chlorobenzyl)-2-[N-methyl-perhydroazepinyl-(4)]-1-(2H)-phthalazine Hydrochloride (Azelastine)," Arzneimittel Forschung Drug Research, Vol. 29, No. 3, pp. 488-493 (1979).	A 000222-000229			FRE 402, 403	
165	Chand, N. "Inhibition of Passive Cutaneous Anaphylaxis (PCA) by Azelastine: Dissociation of its Antiallergic Activities from Antihistaminic and Antiserotonin Properties." Int. J. Immunopharmac. Vol. 7, 1985: 833-38.	A 004966-004971				
166	Chand, N. "Inhibition of Leukotriene (SRS-A)-Mediated Acute Lung Anaphylaxis by Azelastine in Guinea Pigs." Allergy. Vol. 41, 1986: 473-78.					



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PTX	Description	Bates Range	PDX	Admission No Obj.	Objection Basis	Date Admitted
167	Jones, WR. "Quantitative Evaluation of Surface Anesthetics in Albino Mice." J. Pharm Sci. Vol 52, 1963: 500-01.				FRE 402, 403	
168	Chand, N. "Inhibition of Calcium Ionophore (A23187)-Stimulated Histamine Release from Rat Peritoneal Mast Cells by Azelastine: Implications for its Mode of Action." European J. Pharm. Vol. 96, 1983: 227-33.				FRE 402, 403, 802	
169	Fields, D. "Inhibition by Azelastine of Nonallergic Histamine Release from Rat Peritoneal Mast Cells." J. Allergy Clin. Immunol. Vol. 73, 1984: 400-03.				FRE 402, 403, 802	
170	L.H. Hamilton, "Effect of Topical Decongestants on Nasal Airway Resistance," Current Therapeutic Research, Vol. 24, No. 3, pp. 261-268 (August 1978).	A 000213-000221				
171	Kerp, L. "Testing of the Antihistamine HS 592* on Histamine-Induced and "48/80"-Induced Erythema and in Patients with Immediate Allergic Reactions." Med. Welt. Vol. 51, 1966: 2794-98.				FRE 402, 403, 802	
171A	English Translation of Kerp, L. "Testing of the Antihistamine HS 592* on Histamine-Induced and "48/80"-Induced Erythema and in Patients with Immediate Allergic Reactions." Med. Welt. Vol. 51, 1966: 2794-98.				FRE 402, 403, 802	
172	Physicians' Desk Reference, 41st Edition. Ed. Huff. Oradell: Medical Economics Company. Inc., 1987. 961, 1273, 2106.				FRE 402, 403, 802	
173	Web Printout of Novartis: Vibrocil Information				FRE 402, 403, 802	
174	A.A. Kassem, E. Nour El-din, N.M. Murse, A. Abd Elbary and N. Foda, "Formulation and Stabilization of Antazoline Hydrochloride Nasal Drops," Bulletin of the Faculty of Pharmacy, Vol. 15, No. 2, pp. 161-175 (1976).	A 000175-000193				
175	R. Kersten, "Ophthalmic Drugs," Primary Care, Vol. 9, No. 4, pp. 743-756 (December 1982).	A 000350-000365				
176	U.S. Patent No. 2,822,314.	A 006050-006051				
177	U.S. Patent No. 4,749,700.	AS-MEDA 002181-002195				
178	E. Keeney, "Histamine and the Antihistaminic Drugs," California Medicine, Vol. 72, No. 1, pp. 377-389 (May 1950).	A 000089-000104				

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PTX	Description	Bates Range	PDX	Admission No Obj.	Objection Basis	Date Admitted
179	Scudi, JV. "Study of Drug Action on Mammalian Ciliated Epithelium." J. of Pharmacology and Experimental Therapeutics. Vol. 101, 1951: 132-37.				FRE 402, 403	
180	S.M. Fenberg, "Drugs In Allergy," Trans. Amer. Acad. of O&O, Vol. 124 (April 1950), pp. 283-286.	A 000085-000088				
181	Guerrant, JL. "Palpebral Dermatitis." Am. J. Ophthalmol. Vol. 34, 1951: 1318-20.				FRE 402, 403	
182	Orange Book entry for Levocabastine Hydrochloride. <a href="http://www.accessdata.fda.gov">http://www.accessdata.fda.gov</a> . Accessed on 9/9/2007.				FRE 402, 403, 802	
183	U.S. Patent No. 3,144,485.	A 006031-006034				
184	U.S. Patent No. 4,313,931.	A 000329-000339				
185	U.S. Patent No. 4,628,055.	A 006052-006059				
186	U.S. Patent No. 3,878,217.	A 000147-000156				
187	U.S. Patent No. 4,254,129.	A 000294-000304				
188	U.S. Patent No. 4,430,343.	A 000401-000413				
189	U.S. Patent No. 4,728,509.	A 006024-006030				
190	U.S. Patent No. 4,795,754.	A 006035-006041				
191	Astelin Net Sales Figures	AS 006777-006779				
192	Bowser, CS. "New Antihistamine Nasal Spray Safe, with Less Incidence of Bad/Bitter Taste Versus Azelastine." Presented at ACAAI, November 13, 2006.	A 006137-006138			FRE 402, 403, 802	
193	Uniform Jury Instructions for Patent Cases in the United States District Court for the District of Delaware, pp. 40, 43, 55.				FRE 402, 403, 802	
194	Curriculum Vitae of Dr. Richard N. Dalby					
195	Excerpts of ANDA 77-954	A 000942, A 000956, A 000959, A 000965-000967, A 001034, A 001053, A 001400, A 001402				
196	Current Concepts in the Pharmaceutical Sciences: Dosage Form Design and Bioavailability. Ed. Swarbrick. Philadelphia: Lea & Febiger, 1973. 110.				FRE 402, 403	
197	Harris, AS. "Effect of Viscosity on Particle Size Deposition." Journal of Pharmaceutical Sciences. Vol. 77, No. 5, 1988: 405-08.				FRE 402, 403	

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198	Physicians' Desk Reference, 41st Edition. Ed. Huff. Oradell: Medical Economics Company, Inc., 1987. 2005.				FRE 402, 403	
199	The United States Pharmacopeia, 16th Edition. Rockville: United States Pharmacopeial Convention, 1985. 1329.				FRE 402, 403	
200	Chart Illustrating Infringement - Dalby Report Exhibit				FRE 402, 403, 802	
201	List of Previous Expert Testimony				FRE 802	
202	List of Documents Reviewed by Richard N. Dalby				FRE 802	
203	Remington's Pharmaceutical Sciences, 17th Edition. Ed. Gennaro. Eason: Mack Publishing Company, 1985. 63, 82, 441, 1417, 1492-1517.					
204	Webster's Seventh New Collegiate Dictionary. Springfield: G. & C. Merriam & Company, 1967. 31.				FRE 402, 403, 802	
205	The Theory and Practice of Industrial Pharmacy. Ed. Lachman. Philadelphia: Lea & Febiger, 1986. 668.				FRE 402, 403, 802	
206	Curriculum Vitae of Dr. Eli O. Meltzer					
207	Webster's Ninth New Collegiate Dictionary. Springfield: Merriam-Webster Inc., 1983. 364, 640, 738.				FRE 402, 403, 802	
208	Allergy Principles and Practice, 2d Edition. Ed. Middleton, Reed, Ellis. St. Louis: C.V. Mosby Company, 1983. 1101-03, 1112-15.				FRE 402, 403	
209	Allergic Diseases, 3d Edition. Ed. Patterson. Philadelphia: J.P. Lippincott Company, 1985. 206-07, 212-13, 220-27, 378-79.				FRE 402, 403	
210	Goodman and Gilman's The Pharmacological Basis of Therapeutics, 7th Edition. New York: MacMillan Publishing Company, 1985. 9.					
211	Allergic Diseases, 2d Edition. Ed. Patterson. Philadelphia: J.P. Lippincott Company, 1980. 179, 197-98.				FRE 402, 403	
212	Chart Illustrating Infringement - Meltzer Report Exhibit				FRE 402, 403, 802	
213	List of Documents Reviewed by Eli O. Meltzer				FRE 402, 403, 802	
214	Schaffe and Seidmon, "The Intranasal Use of Propenpyridamine Maleate and Chlorphenpyridamine Maleate in Allergic Rhinitis," Annals of Allergy, Vol. 10, 1952: 194-96.	A 008141-008146				
215	RxMed: Pharmaceutical Information - Metreton				FRE 402, 403, 802	

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PTX	Description	Bates Range	PDX	Admission		Date Admitted
				No Obj.	Objection Basis	
216	A. Togias, R.M. Nacario, J. Warner, D. Proud, A. Kagey-Sobotka, I. Nimmagadda, P.S. Norman and L. Lichtenstein, "Demonstration of Inhibition of Mediator Release From Human Mast Cells by Azatadine Base," Journal of the American Medical Association, Vol. 255, No. 2, pp. 225-229 (Jan. 10, 1986).	A 000455-000461				
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219	Physicians' Desk Reference for Nonprescription Drugs. First Edition, pp. 502-03, 506, 522, 539, 553, 616, 637-38, 646, 654-55 (1980).	A 000276-000289				
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222	M. Bende, U. Pipkorn, "Topical levocabastine, a selective HI antagonist, in seasonal allergic rhinoconjunctivitis," Allergy 1987, 42, pp. 512-515.	A 000558-000563				
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PTX	Description	Bates Range	PDX	Admission		Date Admitted
				No Obj.	Objection Basis	
226	Meltzer, EO. "Azelastine nasal spray in the management of seasonal allergic rhinitis." <i>Annals of Allergy</i> . Volume 72, 1994: 354-359.				FRE 402, 403, 802	
227	Gaspar, H. "Comparative efficacy of azelastine nasal spray and terfenadine in seasonal and perennial rhinitis." <i>Allergy</i> . Volume 49, 1994: 152-158.				FRE 402, 403, 802	
228	Weiner, J. "Intranasal corticosteroids versus oral H1 receptor antagonists in allergic rhinitis: systematic review of randomised controlled trials." <i>BMJ</i> . Volume 317, 1998: 1624-1629.				FRE 402, 403, 802	
229	Asta Pharm Report, "Comparison of efficacy and tolerability of azelastine nasal spray, azelastine tablets and astemizole in the treatment of seasonal allergic rhinitis." November 16, 1990.	MPAT 000490-000494			FRE 802	
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236	Intentionally left blank					
237	Intentionally left blank					
238	Apotex's Paragraph IV Certification dated January 24, 2006.	A 000050-000078			FRE 802	



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PTX	Description	Bates Range	PDX	Admission		Date Admitted
				No Obj.	Objection Basis	
239	W. Diamantis, J.E. Harrison, J. Melton, J.L. Perbach, Jr., R.D. Sofia, "In Vivo and In Vitro HI Antagonist Properties of Azelastine," Vol. 23, No. 3, The Pharmacologist (1981), p. 149.	A 000290-000293				
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246	A.J. Bentley and R. T. Jackson, "changes in the Patency of the Upper Nasal Passage Induced by Histamine and Antihistamines," The Laryngoscope, Vol. 80, No. 12, pp. 1859-1870 (1970).	A 000121-000132			FRE 402,403,802	
247	J.A. Blue, "Current Concepts of Allergy of the Eye," Annals of Allergy, Vol. 33, pp. 267-273 (November 1974).	A 000139-000146				
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PTX	Description	Bates Range	PDX	Admission		Date Admitted
				No Obj.	Objection Basis	
251	K. Tatsumi, T. Ou, H. Yamada and H. Yoshimura, "Studies on Metabolic Fate of a New Antiallergic Agent, Azelastine (4-(p-Chlorobenzyl)-2-Methylperhydroazepinyl-(4))-1-(2H)-Phthalazinone Hydrochloride)," Japan J. Pharmacol. Vol. 30, pp. 37-48 (1980).	A 000242-000253				
252	M. Okuda, et al., Oto-Rhino-Laryngology Tokyo, Vol 23, Suppl. 6, pp. 441-461(1980).	A 000254-000275				
252A	English Translation of M. Okuda, et al., Oto-Rhino-Laryngology Tokyo, Vol 23, Suppl. 6, pp. 441-461(1980).					
253	S.W. Lam, R.C. Meyer and L.T. Takahashi, "Determination of Thimerosal in Ophthalmic Solutions by Radial Compression Separation HPLC," Journal of Parenteral Science and Technology, Vol. 35, No. 5, pp.262-265 (September-October 1981).	A 000305-000308			FRE 402, 403, 802	
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PTX	Description	Bates Range	PDX	Admission		Date Admitted
				No Obj.	Objection Basis	
258	N. Chand, J. Pillar, W. Diamantis and R.D. Sofia, "Inhibition of Allergic Histamine Release by Azelastine and Selected Antiallergic Drugs from Rabbit Leukocytes," International Archives of Allergy and Applied Immunology, Vol. 77, No. 4, pp. 451-455 (1985)	A 000435-000441				
259	N.L. Burstein, "The Effects of Topical Drugs and Preservatives on the Tears and Corneal Epithelium in Dry Eye," Trans. Ophthalmol. Soc. U.K., Vol. 104, pp. 402-409 (1985).	A 000442-000449				
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PTX	Description	Bates Range	PDX	Admission		Date Admitted
				No Obj.	Objection Basis	
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268	O.J. Corrado, S. Ollier, M.J. Phillips, J.M. Thomas and R.J. Davies, "Histamine and allergen induced changes in nasal airways resistance measured by anterior rhinomanometry: reproducibility of the technique and the effect of topically administered antihistamine and anti-allergic drugs," Br. J. clin. Pharmacol., Vol 24, No. 3, pp. 283-292 (1987).	A 000548-000557			FRE 402, 403, 802	
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PTX	Description	Bates Range	PDX	Admission		Date Admitted
				No Obj.	Objection Basis	
275	W.E. Berger, S.M. Fineman, P. Lieberman, R.M. Miles and the Rhinitis Study Groups, "Double-blind trials of azelastine nasal spray monotherapy versus combination therapy with loratadine tablets and beclomethasone nasal spray inpatients with seasonal allergic rhinitis," <i>Annals of Allergy, Asthma, &amp; Immunology</i> , Vol. 82, pp. 535-541 (June 1999).	A 000785-000791				
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PTX	Description	Bates Range	PDX	Admission No Obj.	Objection Basis	Date Admitted
283	Excerpts from "Remington's Pharmaceutical Sciences," Fourteenth Ed. (1970) (Title page; Copyright page; Table of Contents (p. xi); Chapter 64 (pp. 1142-1 153); Chapter 80 (pp. 1478-1500); Chapter 83 (pp. 1545-1577); Chapter 85 (pp. 1594-1595; 1597-1625); Chapter 90 (pp. 1729-1733).	A 006444-006370				
284	Website information from Adcock Ingram regarding Antistun-Privin.	A 006011-006015				
285	U.S. Patent No. 4,738,984.	A 006042-006049				
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286A	English Translation of Expert's Report.				FRE 402, 403, 802	
287	H. Breuninger, "Nasentropfen, Ohrentropfen," HNO, pp. 65-68 (March 1971).	A 006107-006110			FRE 402, 403, 802	
287A	English Translation of H. Breuninger, "Nasentropfen, Ohrentropfen," HNC, pp. 65-68 (March 1971).				FRE 402, 403, 802	
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289	"Allergische Rhinitis - Eine Crux Medicorum - Neue Wege in der Therapie," Z. Allg. Med. 57, pp. 1939-1940 (1981)	A 006323-006324				
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291	Subpoena for Naresh Chand	CH 000197-000208				
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PTX	Description	Bates Range	PDX	Admission No Obj.	Objection Basis	Date Admitted
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295	Wallace Laboratories Report No. DR-90-92, "Formula Rationale for Azelastine Hydrochloride Nasal Solution, 0.1 % w/v," January 31, 1991.	ASN 000935-000954			FRE 802	
296	U.S. Patent No. 4,602,099					
297	Plaintiffs Objections and Supplemental Response to Apotex's Interrogatory No. 14.				FRE 802	
298	C.D. Logemann, L.M. Rankin, "Newer Intranasal Migraine Medications," American Family Physician (2000)					
299	Migraine Agents, Medco Health Solutions					
300	Reproduction of Example 24 from German Patent No. 21 64 058 by the Langer Laboratory at MIT					
301	Expert's opinion regarding the use of azelastine or its physiologically compatible salts for nasal and ocular application	MPAT 000277-000279			FRE 402, 403, 802	
302	Decision about the revocation of the European Patent, from the Munich European Patent Office	MPAT 000404-000420			FRE 802	
303	Asta Pharma Report dated September 13 1988	AS-MEDA 003522-003525			FRE 802	
304	USPTO Online Patent Query for 5,164,194				FRE 802	
305	R. Lancaster, "Topical of Systemic Therapy?" pp. 47-53 (1983).	AS-MEDA 001860-001863			FRE 402, 403, 802	
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PTX	Description	Bates Range	PDX	Admission		Date Admitted
				No Obj.	Objection Basis	
308	J. Weiler and E. Meltzer, "Azelastine nasal spray as adjunctive therapy to azelastine tablets in the management of seasonal allergic rhinitis," <i>Annals of Allergy, Asthma, &amp; Immunology</i> , Vol. 79, pp. 327-332 (October 1997).				FRE 406, 403, 802	
309	A. Toggas, D. Proud, A. Kagey-Sobolka, P. Norman, L. Lichtenstein and R. Naclerio, "The effect of a topical tricyclic antihistamine on the response of the nasal mucosa to challenge with cold, dry air and histamine," <i>J. Allergy Clin. Immunol.</i> , Vol. 79, No. 4, April 1987, pp. 599-604.	A 000925-000930			FRE 106	
310	Excerpts from <i>The United States Pharmacopeia - Twenty-First Revision</i> (Official from January 1, 1985), Title page, Copyright page, pp. 1329.1333-1343.1635.1639.1655 and 1657-1660.	AS-MEDA 002113-002133			FRE 106	
311	Excerpts from Remington's <i>Pharmaceutical Sciences</i> , Fourteenth Edition, 1970, Title page, Title Page for Part VIII, pp. 1461-1462, 1492, 1594-1598, 1610 and 1616.	AS-MEDA 002134-002145				
312	Excerpts from Y.W. Chien, "Transnasal Systemic Medications Fundamentals, Development Concepts and Biomedical Assessments," (1985), Title page, pp. 80-81 and 98.	AS-MEDA 002328-002331			FRE 802	
313	N. Chand, "Effect of Azelastine, Its d- and l-Isomers, Putative Metabolites and Analogs on IgE-Mediated Passive Cutaneous Anaphylaxis in Rats," <i>Wallace Laboratories</i> , PH-86-32.	AZ 002575-002585			FRE 802	
314	N. Chand, "Effect of Newer Analogs of Azelastine on Allergic Histamine Secretion from Rat Peritoneal Mast Cells," <i>Wallace Laboratories</i> , PH-89-2.	AZ 002969-002984			FRE 802	
315	N. Chand, "Azelastine Hydrochloride: Influence of Isomers, Metabolites and Analogs of Azelastine and Selected Antiallergic Drugs on Antigen-Induced Contractile Responses and Subsequent Development of Airway Hyperreactivity to Cold in Isolated Rat Trachea," <i>Wallace Laboratories</i> , PH-86-14.	AZ 002388-002422			FRE 802	
316	N. Chand, "Effect of Azelastine, Its Putative Metabolites, Isomers and Analogs on Calcium Ionophore A23187-Stimulated Leukotriene B4 Synthesis in Rat Peritoneal Cells (Radiomunoassay)," <i>Wallace Laboratories</i> , PH-86-35.	AZ 002614-002635			FRE 802	

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PTX	Description	Bates Range	PDX	Admission No Obj.	Objection Basis	Date Admitted
317	N. Chand, "Influence of Azelastine, Its Metabolites and Analogs on Aeroallergen-Induced Pulmonary Mechanics Changes in Guinea Pig Asthma Model," Wallace Laboratories, PH-85-10.	AZ 002216-002223			FRE 802	
318	N. Chand, "Antagonism of Histamine by Azelastine, Its Isomers, Putative Metabolites and Analogs in Isolated Guinea Pig Ileum," Wallace Laboratories, PH-86-16.	AZ 002423-002440			FRE 802	
319	J.M. Weiler, A. Donnelly, B.H. Campbell, J.T. Connell, L. Diamond, L.H. Hamilton, R.R. Rosenthal, G.R. Hensworth and J.L. Perbach, Jr., "Multicenter, double-blind, multiple-dose, parallel-groups efficacy and safety trial of azelastine, chlorpheniramine, and placebo in the treatment of spring allergic rhinitis," J. Allergy Clin. Immunol., Vol. 82, No. 5, Part 1, pp. 801-811 (November 1988).	A 000931-000941			FRE 402, 403, 802	
320	T. Fukunake, "Studies of clinical effect of E - 0659 on the so - called vasomotor rhinitis," Study No. 120, Degussa GB Pharma Report, (1983).	ASN 074954-074964			FRE 802	
321	D.K. Ledford, "Chapter 9, Rhinitis" and P. Lieberman, "Chapter 17, Antihistamines," Allergic Diseases - Diagnosis and Treatment, Cover page, Copyright page, pp. 159-182 (2nd Ed. 2000).				FRE 402, 403, 802	
322	Allergy Principles & Practice, "Allergic and Nonallergic Rhinitis," pp. 1005, 1014 & "Chapter 45 -Antihistamines," (5th Ed. 1998).					
323	Asthma and Rhinitis, "Chapter 100," p. 1330 (1995).					
324	Hill et al., (1978) Med J. Austr. 2:603-4.					
325	Gale et al., (1980) Clin. Allergy 10:527-33.					
326	Fokkens et al. (2007) Allergy 62:1078-84.				FRE 402, 403, 802	
327	Bielory et al., (2007) Medscape General Medicine 9:35.				FRE 402, 403, 802	
328	Andersen, et al., (1987) Allergy 42:343-51.				FRE 402, 403, 802	
329	German Offenlegungsschrift DE 35 30793					
329A	English Translation of German Offenlegungsschrift DE 35 30793					
330	P 34 33 776.8					
330A	English Translation of P 34 33 776.8					



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PTX	Description	Bates Range	PDX	Admission		Date Admitted
				No Obj.	Objection Basis	
331	Memorandum entitled Memo for Dr Aurich dated September 30 1985	AS-MEDA 009924			FRE 802	
331A	English Translation of Memorandum entitled Memo for Dr Aurich dated September 30 1985				FRE 802	
332	German Offenlegungsschrift 21 64 058					
332A	English Translation of German Offenlegungsschrift 21 64 058					
333	Declaration Under Rule 132 of Dr Achterrath-Tuckermann dated February 16 1987				FRE 802	
334	Declaration of Dr Szelenyi dated January 23 1990	MP 000063-64			FRE 802	
335	European Patent No 316 633					
335A	English Translation of European Patent No 316 633					
336	Decision of the Opposition Division of the European Patent Office mailed March 28 1996				FRE 402, 403, 802	
336A	English Translation of Decision of the Opposition Division of the European Patent Office mailed March 28 1996				FRE 402, 403, 802	
337	Decision of the Technical Court of Appeals 3.3.2 dated April 2000				FRE 402, 403, 802	
337A	English Translation of Decision of the Technical Court of Appeals 3.3.2 dated April 2000				FRE 402, 403, 802	
338	U.S. Patent No 3813384					
339	December 1982 Asia-Werke AG Toxicology Report	ATI 001098-001266			FRE 402, 403, 802	
340	Abstract 76 Chand Nolan Diamantis Sofia R.D 1985 Pharmacologist 27162				FRE 402, 403, 802	
341	Single page document with Beispiel 24	AS-MEDA 001568			FRE 802	
341A	English Translation of Single page document with Beispiel 24				FRE 802	
342	Internal Letter dated September 1985 from Dr Aurich to Prof Dr Breuel	AS-MEDA 000601-000602			FRE 802	
342A	English Translation of Internal Letter dated September 1985 from Dr Aurich to Prof Dr Breuel				FRE 802	
343	Internal Memo prepared by Dr Hettche to Dr Herbst dated August 13 1990	AS-MEDA 001345			FRE 802	
343A	English Translation of Internal Memo prepared by Dr Hettche to Dr Herbst dated August 13 1990				FRE 802	
344	Handwritten note by Dr Hettche dated February 18 1986	AS-MEDA 001938			FRE 802	

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PTX	Description	Bates Range	PDX	Admission		Date Admitted
				No Obj.	Objection Basis	
344A	English Translation of Handwritten note by Dr Hettche dated February 18, 1986				FRE 802	
345	Handwritten note by Dr Hettche to Dr Ulbrich dated August 12, 1987	AS-MEDA 000600			FRE 802	
345A	English Translation of Handwritten note by Dr Hettche to Dr Ulbrich dated August 12, 1987				FRE 802	
346	German Patent Application No 3539873.6				FRE 402, 403, 802	
346A	English Translation of German Patent Application No 3539873.6				FRE 402, 403, 802	
347	Antistun-Privin package insert				FRE 402, 403, 802	
348	Single page 725 taken from reference involving Medications for the eye ear and nose	AS-MEDA 007755			FRE 402, 403, 802	
348A	English Translation of Single page 725 taken from reference involving Medications for the eye ear and nose				FRE 402, 403, 802	
349	Aberer Tappeiner 1988 Wiener klinische Wochenschrzfi 1988 Dec 2; 100(23):763-765.				FRE 402, 403, 802	
349A	English Translation of Aberer Tappeiner 1988 Wiener klinische Wochenschrzfi 1988 Dec 2; 100(23):763-765.				FRE 402, 403, 802	
350	Document entitled Inhibition of allergic histamine release from rat peritoneal mast cells attached as part of Dr Szelenyis January 23, 1990 Declaration				FRE 802	
351	Declaration of Dr Istvan Szelenyi dated June 1, 1990				FRE 802	
352	1988-02-22 Asia "Expert Report on Chemical and Pharmaceutical Documentation according to § 24 (1) AMG 1976 Azelastine Intranasal Spray"	AS 003212-003236			FRE 402, 403, 802	
353	Assignment Agreement	AS 007016-007027			FRE 802	
354	Schedule E - Assignment and Assumption Agreement	AS 007028-007033			FRE 802	
355	Exhibit B - License Agreement	AS 007034-007036			FRE 802	
356	Exhibit C - Amendment to Azelastine License Agreement	AS 007037-007038			FRE 802	
357	1996-07-31 Letter from Black to Engel re 1982-08-16 License Agreement	AS 007039-007040			FRE 802	
358	2001-04-11 Letter from Stewart to Levine re 1982-08-16 License Agreement	AS 007041-007042			FRE 802	
359	2001-04-11 Letter from Levine and Stewart to Peterseim re 1982-08-16 License Agreement	AS 007043-007044			FRE 802	

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PTX	Description	Bates Range	PDX	Admission No Obj.	Objection Basis	Date Admitted
360	2002-05-17 Interest Purchase Agreement	AS 007045-007067			FRE 802	
361	Exhibit A - Agreement	AS 007068-007079			FRE 802	
362	Schedule III - Patent Assignment	AS 007080-007085			FRE 802	
363	Schedule IV - Letter dated July 31, 1996 (To be attached)	AS 007086-007088			FRE 802	
364	1987-02-27 Wallace draft minutes of the February 10-11, 1987 azelastine satellite meeting	AS 007208-007235			FRE 802	
365	1982-08-16 License Agreement between Carter-Wallace and Chemiewerk Homburg	AS 007908-007950			FRE 802	
366	Alcon Press Release re Opatanol	ASC 000001			FRE 402, 403, 802	
367	"Questions and Answers on the Withdrawal of an Application for an Extension of the Marketing Authorisation for Opatanol"	ASC 000002-000003			FRE 402, 403, 802	
368	Lieberman, Efficacy of azelastine nasal spray in the treatment of vasomotor (perennial nonallergic) rhinitis (2001)	ASC 000004-000011			FRE 402, 403, 802	
369	Berger, Double-blind trials of azelastine nasal spray monotherapy versus combination therapy with loratadine tablets and beclomethasone nasal spray in patients with seasonal allergic rhinitis (1999)	ASC 000012-000018			FRE 402, 403, 802	
370	Berger, Efficacy of azelastine nasal spray in patients with an unsatisfactory response to loratadine (2003)	ASC 000019-000027			FRE 402, 403, 802	
371	Charpin, A multicenter clinical study of the efficacy and tolerability of azelastine nasal spray in the treatment of seasonal allergic rhinitis: a comparison with oral cetirizine (1995)	ASC 000028-000033			FRE 402, 403, 802	
372	Ciprandi, Treatment of nonallergic perennial rhinitis (2004)	ASC 000034-000042			FRE 402, 403, 802	
373	Conde Hernandez, DJ. "Comparison of Azelastine Nasal Spray and Oral Ebastine in Treating Seasonal Allergic Rhinitis." Curr. Med. Res. Opin. Volume 13, 1995: 299-304.	ASC 000043-000048			FRE 402, 403, 802	
374	Corre, Effectiveness of Azelastine Nasal Spray Compared with Oral Cetirizine in Patients with Seasonal Allergic Rhinitis (2005)	ASC 000049-000061			FRE 402, 403, 802	
375	Davies, Antihistamines: topical vs oral administration (1996)	ASC 000062-000070			FRE 402, 403, 802	
376	Dorow, Efficacy and tolerability of Azelastine Nasal Spray in Patients with Allergic Rhinitis Compared to Placebo and Budenoside (1993)	ASC 000071-000074			FRE 402, 403, 802	

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PTX	Description	Bates Range	PDX	Admission No Obj.	Objection Basis	Date Admitted
377	Falsera, Comparative Efficacy and Safety of Azelastine and Levocabastine Nasal Sprays in Patients with Seasonal Allergic Rhinitis (2001)	ASC 000075-000081			FRE 402, 403, 802	
378	2006-02-14 Letter from Matthews to Brasseur re Opatanol	ASC 000082			FRE 402, 403, 802	
379	Gambardella, A Comparison of the Efficacy of Azelastine Nasal Spray and Loratidine Tablets in the Treatment of Seasonal Allergic Rhinitis (1993)	ASC 000083-000092			FRE 402, 403, 802	
380	Gaspar, Investigation of Long-term Efficacy and Tolerability of Azelastine Nasal Spray in the Treatment of Perennial Allergic Rhinitis (1993)	ASC 000100-000106			FRE 402, 403, 802	
381	Gaspar, Intranasal Treatment of Perennial Allergic Rhinitis: Comparison of azelastine nasal spray and budesonide nasal aerosol (1993)	ASC 000107-000111			FRE 402, 403, 802	
382	Herman, A randomized double-blind placebo controlled study of azelastine nasal spray in children with perennial rhinitis (1997)	ASC 000112-000120			FRE 402, 403, 802	
383	Horak, Azelastine nasal spray and desloratadine tablets in pollen-induced seasonal allergic rhinitis: a PD study of onset of action and efficacy (2006)	ASC 000121-000129			FRE 402, 403, 802	
384	LaForce, Efficacy of azelastine nasal spray in seasonal allergic rhinitis patients who remain symptomatic after treatment with fexofenadine (2004)	ASC 000130-000135			FRE 402, 403, 802	
385	Lieberman, Management of allergic rhinitis with a combination anti-histamine/anti-inflammatory agent (1999)	ASC 000136-000141			FRE 402, 403, 802	
386	Meltzer, Efficacy of azelastine in perennial allergic rhinitis: Clinical and rhinomanometric evaluation (1987)	ASC 000142-000150			FRE 402, 403, 802	
387	Passali, A Comparison of Azelastine Nasal Spray and Cetirizine Tablets in the Treatment of Allergic Rhinitis (1994)	ASC 000151-000159			FRE 402, 403, 802	
388	Ratner et al., (1994) J. Allergy Clin. Immunol. 94:818-25	ASC 000160-000168			FRE 402, 403, 802	
389	W.W. Storns, D.S. Pearlman, P. Chervinsky, J. Grossman, P.C. Halverson, J.I. Freitag and M.D. Widlitz, "Effectiveness of Azelastine Nasal Solution in Seasonal Allergic Rhinitis," ENT, Vol. 73, No. 6 (June 1994), pp. 382-394 (including Front Cover and Copyright page).	ASC 000169-000179			FRE 402, 403, 802	



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PTX	Description	Bates Range	PDX	Admission		Date Admitted
				No Obj.	Objection Basis	
390	van de Heming, A gap in surface therapy: topical antihistamines (1991)	ASC 000196-000202			FRE 402, 403, 802	
391	Wang, Effect of Topical Applications of budesonide and Azelastine on Nasal Symptoms, Eosinophil Count and Mediator Release in Atopic Patients after Nasal Allergen Challenge during the Pollen Season (1997)	ASC 000203-000212			FRE 402, 403, 802	
392	Wober, Evaluation of the Drug Monitoring Programme of Azelastine Hydrochloride Nasal Spray in the Treatment of Allergic Rhinitis in Children under 13 Years of Age (1997)	ASC 000213-000217			FRE 402, 403, 802	
393	Wober, Efficacy and tolerability of azelastine nasal spray in the treatment of allergic rhinitis: large scale experience in community practice (1997)	ASC 000218-000228			FRE 402, 403, 802	
394	Gaspar, Azelastine nasal spray relieves symptoms of allergic rhinitis (1990)	ASN 038857-038858			FRE 402, 403, 802	
395	Gaspar, Azelastine nasal spray relieves symptoms of allergic rhinitis (Abstract) (1990)	ASN 038869			FRE 402, 403, 802	
396	Asta Clinical Study No. A 5610-2610, Comparison of the Efficacy and Tolerability of an Azelastine HCl Nasal Spray with those of Terfenadine on Six-Week Treatment of Patients with Allergic Rhinitis (Seasonal)	ASN 038878-038881			FRE 402, 403, 802	
397	Asta Clinical Study No. A 5610-2606, Comparison of the Efficacy and Tolerability of an Azelastine HCl Nasal Spray with those of Terfenadine on Six-Week Treatment of Patients with Allergic Rhinitis (Seasonal)	ASN 052451-052453			FRE 402, 403, 802	
398	Asta Clinical Study No. A 5610-2613, Comparison of the Efficacy and Tolerability of an Azelastine HCl Nasal Spray with those of Terfenadine on Six-Week Treatment of Patients with Allergic Rhinitis (Seasonal)	ASN 054262-054264			FRE 402, 403, 802	
399	Summary of Efficacy Studies re: Azelastine	ASN 075390-075417			FRE 402, 403, 802	
400	1984-12-20 Memo re: Meeting with Chemiewerk Homburg and Organon, December, 1984	AZ 000102-000109			FRE 402, 403, 802	
401	1986-09-04 Wallace Labs Report No. TC-865-15 re: Summary of Toxicology Studies	AZ 005761-005803			FRE 802	

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PTX	Description	Bates Range	PDX	Admission No Obj.	Objection Basis	Date Admitted
402	1984-08-09 Asta Report on the Testing of the Primary Cutaneous Irritation (Local Irritancy) of two Formulations of Azelastine Hydrochloride (Cream, Gel) after repeated Application to the Skin of the Rabbit (Patch-Test)	AZ 006124-0006159			FRE 402, 403, 802	
403	Apotex's Response to Plaintiff's First Request for the Production of Documents and Things				FRE 402, 403, 802	
404	Apotex, Inc. and Apotex Corp.'s Responses to Plaintiff's First Set of Interrogatories					
405	Apotex's First Supplemental Response to Plaintiff's First Set of Interrogatories					
406	Apotex's First Supplemental Response to Plaintiff's First Set of Requests for Admission					
407	Ansel, "Introduction to Pharmaceutical Dosage Forms" (pp. 333-349)	A 000194-000212				
408	Azelastine Hydrochloride Nasal Spray 137mcg: Listed Drug Labeling - Bottle Label	A 000981-000983			FRE 402, 403	
409	Azelastine Hydrochloride Nasal Spray 137mcg: Listed Drug Labeling - Carton	A 000984-000988			FRE 402, 403	
410	Cheng, D. Y., "Cascade Impactor Method for the Droplet Size Characterization of a Metered-Dose Nasal Spray," J. Pharma. Sci., Vol. 73, No. 3, March 1984, pp. 344-348.	A 005981-005985			FRE 402, 403, 802	
411	Taschenbuch der praktischen Medizin	AS-MEDA 000366-000368			FRE 402, 403, 802	
412	Pharmazeutische Technologie	AS-MEDA 000615-000618			FRE 402, 403, 802	
413	Externe Therapie von Hautkrankheiten	AS-MEDA 000639-000646			FRE 402, 403, 802	
414	Asta Pharma Report re "Azelastine HCl 0.1%: Effects on ciliary activity of guinea pig nasal mucosa after local administration" (1992)	AS-MEDA 001224-001225			FRE 402, 403, 802	
415	Centre de Recherches Biologiques Report re "Azelastine HCl 0.1%: Effects on ciliary activity of guinea pig nasal mucosa after local administration"	AS-MEDA 001226-001249			FRE 402, 403, 802	
416	Funktionelle Dermatologie	AS-MEDA 009081-009082			FRE 402, 403, 802	

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PTX	Description	Bates Range	PDX	Admission		Date Admitted
				No Obj.	Objection Basis	
417	6.9.1985 Degussa Memo from Aurich to Hettche re Azelastin-Nasenspray	AS-MEDA 009738				
418	Chand et al., "Inhibition of Leukotriene (SRS-A)-mediated allergic bronchospasm by Azelastine, a Novel <i>Orally Effective</i> Antasthmatic Drug," 241 The Journal of Allergy and Clinical Immunology (1983)					
419	Chand et al., "Inhibition of IgE-mediated passive cutaneous anaphylaxis (PCA) by azelastine in rat," The Journal of Allergy and Clinical Immunology (1984)					
420	Chand et al., "Dissociation of Antiallergic (Anti-PCA) Activity From the Antihistaminic and Antiserotonin Activities of Azelastine," 138 The Pharmacologist (1984).					
421	Chand et al., "Inhibition of Allergic Histamine Secretion From RPMC by Azelastine, a Novel. <i>Orally Acting</i> Antiallergic Agent, 419 The Pharmacologist (1983).					
422	Chand et al., "Inhibition of IgE-mediated Allergic Histamine Release by Azelastine from Rabbit Basophils," Federal Proceedings (1984)					
423	Chand et al., "Antagonism of Leukotrienes, Calcium and Histamine by Azelastine," The Pharmacologist (1984)					
424	Chand et al., "Pharmacological Modulation of In Vitro Anaphylactic Responses of Isolated Guinea Pig Tracheal Rings by Azelastine and Inhibitors of Arachidonic Acid (AA) Metabolism," Federation Proceedings (1984)					
425	Chand et al., "Antagonism of histamine and leukotrienes by azelastine in isolated guinea pig ileum," Agents and Actions, vol. 19 (1986)					
426	Chand et al., "Inhibition of Antigen-induced Airway Hyperreactivity (AIH) to Cold Provocation by Azelastine and Selected Antasthmatic Drugs in Rat Isolated Tracheal Segments," 130 Journal of Allergy and Clinical Immunology (1/1987)					



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PTX	Description	Bates Range	PDX	Admission No Obj.	Objection Basis	Date Admitted
427	Chand et al., "Effect of Azelastine and Diltiazem on Activation (First) and Release (Second) Stages of Allergic Histamine Secretion in Rabbit Leukocytes," Federation Proceedings (3/1987)					
428	Chand et al., "Inhibition of 5-HETE, LTB4 and LTC4 Synthesis by Azelastine and its d- and l- Isomers in Rat Mixed Peritoneal Cells," American Review of Respiratory Disease (4/1987)					
429	Chand et al., "Inhibition of <i>Acute Bronchial Anaphylaxis</i> by Azelastine (AZ) in Aerosolized-Sensitized Guinea Pig (GP)," 671 Annals of Allergy (1985)					
430	USP 5164194 Patent Assignment Abstract of Title	MPAT 000187-000188			FRE 402, 403	
431	USP 5164194 Maintenance Fee Statement	MPAT 000189-000191			FRE 402, 403	
432	Azelastine Assignment Document from Hettche	MPAT 000192-000194			FRE 402, 403	
433	ASTA Conveyance Document re Name Change	MPAT 000195-000196			FRE 402, 403	
434	ASTA Conveyance Document re Name Change	MPAT 000197-000206			FRE 402, 403	
435	Viatrix Conveyance Document re Assignment	MPAT 000207-000213			FRE 402, 403	
436	USPTO Notice of Recordation of Assignment Document	MPAT 000214-000223			FRE 402, 403	
437	MedPointe Conveyance Document re Security Agreement	MPAT 000224-000230			FRE 402, 403	
438	Hettche Questionnaire					
439	Hettche Deposition Transcript					
439A	English Translation of Hettche Deposition Transcript					
440	Szelenyi Questionnaire					
441	Szelenyi Deposition Transcript					
441A	English Translation of Szelenyi Deposition Transcript					
442	Engel Questionnaire					
443	Engel Deposition Transcript					
443A	English Translation of Engel Deposition Transcript					
444	Cirillo, Pharmacology and Therapeutic Use of Antihistamines. Am J. Hosp Pharm 33: 1200-1207 (Nov) 1976.	AS-MEDA 000040-000046			FRE 402, 403, 802	
445	Hunnus Pharmazeutisches Wörterbuch	AS-MEDA 000242-000244			FRE 402, 403, 802	
446	Romp Chemie Lexikon	AS-MEDA 000245-000246			FRE 402, 403, 802	
447	27. Jan. 1986 Notiz für Herrn Dr. Herbst from Dr. Hettche	AS-MEDA 004168-004169				

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PTX	Description	Bates Range	PDX	Admission No Obj.	Objection Basis	Date Admitted
447A	English Translation of 27. Jan. 1986 Notiz fur Herrn Dr. Herbst from Dr. Hettche					
448	Asta Pharma Report re "Azelastine HCl 0.1%: Effects on ciliary activity of guinea pig nasal mucosa after local administration" (1992)	AS-MEDA 000691-000692			FRE 402, 403, 802	
449	Fisher, Contact Dermatitis from Topical Medicaments (1982).	AS-MEDA 001214-001222			FRE 402, 403, 802	
450	Treatment of Seasonal Perennial Rhinitis, British Medical Journal 283: 1981.	AS-MEDA 001288-001290			FRE 402, 403, 802	
451	Achteirath-Tuckermann, Experimental Studies on Acute and Chronic Action of Azelastine on Nasal Mucosa in Guinea Pigs, Rats and Dogs	AS-MEDA 001962-001966				
452	Reynolds, Martindale: The Extra Pharmacopoeia	AS-MEDA 002009-002011			FRE 402, 403, 802	
453	Biopharmazie	AS-MEDA 005739-005741			FRE 402, 403, 802	
454	13.08.90 Memo from Hettche to Herrn and Herbst	AS-MEDA 007806-007806			FRE 402, 403, 802	
455	Externe Therapie Von Hautkrankheiten	AS-MEDA 008489-008490			FRE 402, 403, 802	
456	Textbook Of Dermatology Volume One Third Edition	AS-MEDA 008491-008494			FRE 402, 403, 802	
457	Funktionelle Dermatologie Grundlagen Der Morphokinetik Pathophysiologie, Pharmakoanalyse Und Therapie Von Dermatosen	AS-MEDA 008495-008496			FRE 402, 403, 802	
458	Patent No. 1,377,231	AS-MEDA 009862-009873				
459	12.08.87 Memo from Hettche to Ulbrich re Azelastin Nasenspray	AS-MEDA 009938-009938			FRE 402, 403, 802	
460	Medpointe Spreadsheets re Astelin Monthly NRx, TRx, TRx EU (1/97-6/06)	AS 006780-006833			FRE 402, 403, 802, 1006	
461	Medpointe Spreadsheet re Astelin Monthly Net Sales (1/97-5/07)	AS 007951-007954			FRE 402, 403	
462	Medpointe Spreadsheet re Astelin Monthly TRx (7/06-5/07)	AS 007955-007957			FRE 402, 403, 802, 1006	
463	Medpointe Spreadsheet re Astelin Monthly TRx EU (7/06-5/07)	AS 007958-007960			FRE 402, 403, 802, 1006	

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464	Medpointe Spreadsheet re Astelin Monthly NRx (7/06-5/07)	AS 007961-007963			FRE 402, 403, 802, 802, 2006	
465	Medpointe Spreadsheet re Astelin Monthly TRx (6/07-11/07)	AS 008695			FRE 402, 403, 802, 2006	
466	Medpointe Spreadsheet re Astelin Monthly Net Sales (1/97-12/07)	AS 008696-008697			FRE 402, 403	
467	Influence of Azelastine, Administered After Antigen Challenge, on Acute Lung Anaphylactic Responses in Guinea Pigs - PH-85-5	AZ 004191-004203				
468	Berger, "Impact of azelastine nasal spray on symptoms and quality of life compared with cetirizine oral tablets in patients with seasonal allergic rhinitis" Annals of Allergy 97 (2006), DX 48				FRE 402, 403, 802	
469	Byrn, Graber and Midland. "Comparison of the Solid and Solution Conformation of Methallylamine, Trpelenamine...", J. Org. Chem., Vol. 41, No. 13, 1976				FRE 402, 403, 802	
470	Morris et al. "Advances in Pharmaceutical Materials and Processing." PSIT Vol. 1, No. 6, September 1998.				FRE 402, 403, 802	
471	Remington's excerpt (1985) - pg. 441				FRE 402, 403, 802	
472	Apotex ANDA excerpts	A 000956-000967; A 001025-001052; A 001399-001405			FRE 402, 403	
473	Bioequivalency Amendment	A 007932-007937			FRE 402, 403	
474	The Random House Dictionary; p. 71 (definition of ampule)		200		FRE 402, 403	
475	Black's Medical Dictionary; p. 31 (definition of ampoule)		201		FRE 402, 403	
476	The Wiley Encyclopedia of Packaging Technology; pp. 16-20, 506-509, 720 ("ampuls and vials" "pharmaceutical packaging")		202		FRE 402, 403	
477	Chand, N. "Inhibition of Leukotriene (SRS-A)-Mediated Allergic Bronchospasm by Azelastine, a Novel Orally Active Antinasthmatic Drug."		203		FRE 402, 403	
478	Diamantis, W. "Inhibition of IgE-mediated Passive Cutaneous Anaphylaxis (PCA) by Azelastine in Rat"		204		FRE 402, 403, 802	
479	Chand, N. "Inhibition of Acute Bronchial Anaphylaxis by Azelastine (AZ) in Aerosol-Sensitized Guinea Pig (GP) Asthma Model."		205		FRE 402, 403, 802	
480	Chand, N. "Inhibition of Leukotriene (SRS-A)-Mediated Acute Lung Anaphylaxis by Azelastine in Guinea Pigs."		206		FRE 402, 403, 802	

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PTX	Description	Bates Range	PDX	Admission No Obj.	Objection Basis	Date Admitted
481	Chand, N. "Inhibition of Antigen-Induced Airway Hyperreactivity (IAH) to Cold Provocation by Azelastine and Selected Antasthmatic Drugs in Rat Isolated Tracheal Segments."		207		FRE 402, 403, 802	
482	Chand, N. "Inhibition of 5-Hete... Synthesis by Azelastine and its d- and l-isomers in Rat Mixed Peritoneal Cells."		208		FRE 402, 403, 802	
483	Apotex ANDA excerpts	A 000965-000967; A 001400			FRE 402, 403	
484	Acrosols in Medicine excerpts	A 006221-006222; A 006230-006249; A 006311			FRE 402, 403, 802	
485	Ansel, "Introduction to Pharmaceutical Dosage Forms"	A 000194-000195; A 000208-000212			FRE 402, 403, 802	
486	Remington's excerpt (1985) - pp. 82, 1500				FRE 402, 403, 802	
487	Remington's excerpt (1970)				FRE 402, 403, 802	
488	US Pharmacopeia re overages; pp. 1137 - 1138	A 006444-006445; A 006459-006481			FRE 402, 403, 802	
489	Orget et al., Comparison of Intranasal Cromolyn Sodium and Oral Terfenadine for Allergic Rhinitis (abstract) Journal of Allergy and Clinical Immunology 1988; 81:351				FRE 402, 403, 802	
490	Meltzer et al., An Open Label Study of Azelastine Nasal Spray in the Treatment of Nasal Congestion in Patients with Seasonal Allergic Rhinitis (abstract) Ann. Allergy Asthma Immunol. 2004; 92: 137-138				FRE 402, 403, 802	
491	Meltzer et al., Azelastine nasal spray significantly improves health related quality of life compared to cetirizine tablets in patients with seasonal allergic rhinitis (SAR). (abstract) J. Allergy Clin. Immunol. 2006; 117:S324				FRE 402, 403, 802	
492	Bronsky et al., Cardiac safety of azelastine following 8 weeks of intranasal administration (abstract) J. Allergy Clin. Immunol. 1997; 99:S445				FRE 402, 403, 802	
493	Meltzer et al., Evaluation of the safety/efficacy of azelastine nasal spray in seasonal allergic rhinitis (abstract) Clin. Exper. Allergy 1990; 20: 100				FRE 402, 403, 802	



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PTX	Description	Bates Range	PDX	Admission		Date Admitted
				No Obj.	Objection Basis	
494	Weiler et al., A Safety and Efficacy Evaluation of Azelastine (AZ) Nasal Spray (NS) in Seasonal Allergic Rhinitis (SAR) (abstract) J. Allergy Clin. Immunol. 1991; 87:219				FRE 402, 403, 802	
495	Allergic Diseases: Diagnosis and Management, Fourth Edition. Ed. Patterson. Philadelphia: J.B. Lippincott Company, 1993. 242-49				FRE 402, 403, 802	
496	The Merck Index, 10th Edition. Ed. Windholtz. Rahway: Merck & Co. Inc., 1983. 150				FRE 402, 403, 802	
497	Handbook of Nonprescription Drugs, 7th Edition (1982) (Title page; Copyright page; Table of Contents; pp. 166-169 and 428-430)				FRE 402, 403, 802	
498	Allergic Diseases, 2d Edition. Ed. Patterson. Philadelphia: J.P. Lippincott Company, 1980. 179-203				FRE 402, 403, 802	
499	Allergic Diseases, 3d Edition. Ed. Patterson. Philadelphia: J.P. Lippincott Company, 1985. 64-101, 206-231, 374-407, 758-93				FRE 402, 403, 802	
500	Allergy Principles and Practice, 2d Edition. Ed. Middleton, Reed, Ellis. St. Louis: C.V. Mosby Company, 1983. 118-47, 270-303, 382-435, 574-633, 770-803, 1100-1143				FRE 402, 403, 802	
501	Bousquet J. "ARIA in the pharmacy: management of allergic rhinitis symptoms in the pharmacy." Allergy, Vol. 59, 2004: 373-387				FRE 402, 403, 802	
502	Dykewicz, MS. "Executive Summary of Joint Task Force Practice Parameters on Diagnosis and Management of Rhinitis." Annals of Allergy. Vol. 81, 1998: 463-468				FRE 402, 403, 802	
503	Garbe, E. "Inhaled and nasal glucocorticoids and the risks of ocular hypertension or open-angle glaucoma." Allergy. Volume 277, 1997: 722-727				FRE 402, 403, 802	
504	Grossman J. "Onset of Action and Patient Acceptance of Azelastine in a Nasal Spray formulation." Abstracts from XVth International Congress of Allergology and Clinical Immunology. 1997				FRE 402, 403, 802	

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PTX	Description	Bates Range	PDX	Admission		Date Admitted
				No Obj.	Objection Basis	
505	Meltzer, E.O. "A dos-ranging study of the efficacy and safety of azelastine nasal spray in the treatment of seasonal allergic rhinitis with an acute model." J Allergy Clin Immunol. Volume 94, 1994: 972-980				FRE 402, 403, 802	
506	Meltzer, E.O. "A dose-response study of the bronchodilator action of azelastine in asthma." J Allergy Clin Immunol. volume 79, 1987: 893-899				FRE 402, 403, 802	
507	Meltzer, E.O. "A step approach to the clinical management of allergic rhinitis: prescription and over-the-counter reference summary." Managed Care Interface. Volume 12, 1999:70-77				FRE 402, 403, 802	
508	Meltzer, E.O. "An overview of current pharmacotherapy in perennial rhinitis." J Allergy Clin Immunol. Volume 95, 1995:1097-1110				FRE 402, 403, 802	
509	Meltzer, E.O. "Beclomethasone dipropionate nasal aerosol spray in allergic rhinitis: a comparison of three delivery systems." Ann Allergy. Volume 55, 1985:802-804				FRE 402, 403, 802	
510	Meltzer, E.O. "Double-blind assessment of azelastine in the treatment of perennial allergic rhinitis." Ann Allergy. Volume 73, 1994:141-146				FRE 402, 403, 802	
511	Meltzer, E.O. "Effects of azelastine nasal spray on individual rhinitis symptoms." (abst) Ann Allergy Asthma Immunol. Volume 78, 1997:143				FRE 402, 403, 802	
512	Meltzer, E.O. "Evaluation of symptom relief, nasal airflow, nasal cytology, and acceptability of two formulations of flunisolide nasal spray in patients with perennial allergic rhinitis." Ann Allergy. Volume 64, 1990:536-540				FRE 402, 403, 802	
513	Meltzer, E.O. "Evaluation of the optimal oral antihistamine for patients with allergic rhinitis." May Clin Proc. Volume 80, 1995:1170-1176				FRE 402, 403, 802	

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PTX	Description	Bates Range	PDX	Admission		Date Admitted
				No Obj.	Objection Basis	
514	Meltzer, E.O. "Intranasal steroids: managing allergic rhinitis and tailoring treatment to patient preference." Allergy and Asthma Proc. Volume 26, 2005: 445-451				FRE 402, 403, 802	
515	Meltzer, E.O. "Olopatadine HCl nasal spray is effective and safe for the treatment of seasonal allergic rhinitis." (abst) Ann Allergy Asthma Immunol. Volume 92, 2004:103				FRE 402, 403, 802	
516	Meltzer, E.O. "Pharmacological treatment options for allergic rhinitis and asthma." Clin Exp Allergy. Volume 28, 1998:27-36				FRE 402, 403, 802	
517	Meltzer, E.O. "Rhinitis not just hay fever." Patient Care. Volume 23, 1989:168-184				FRE 402, 403, 902	
518	Meltzer, E.O. "The current outlook on chronic allergic rhinitis." J Respir Dis. Volume 6, 1985:100-123				FRE 402, 403, 902	
519	Opatowsky, I. "Intraocular pressure elevation associated with inhalation and nasal corticosteroids." Ophthalmology. Volume 102, 1995:177-179				FRE 402, 403, 902	
520	"Steroid-Free Astelin (R) Nasal Spray (R) Demonstrated Seasonal Allergy Symptom Improvement Within 15 Minutes in Clinical Study." www.medicalnewstoday.com. Accessed on 06-28-2007.	ASC 000229-000230			FRE 402, 403, 902	
521	Letter from Hankin to Carter-Wallace re Astelin Marketing	A 006439-006443			FRE 402, 403, 802	



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PTX	Description	Bates Range	PDX	Admission No Obj.	Objection Basis	Date Admitted
522	Aerosols in Medicine: Principles, Diagnosis and Therapy. Ed. Moren, newhouse, and Dolovich. Amsterdam:Elsevier, 1985. Pgs: Cover, Title, Copyright (A06220-22), xi-xvii (A06223-29), 1-20 (A06230-49), 53-76 (A06250-73), 123-147 (A06274-98), 193-197, 198-199 (A06299-6300), 200-206, 207-209 (A06301-03), 210-217, 251-262 (A06304-05), 263-267, 268-272 (A06306-10), 273-282, 283-284 (A06311-12), 285-287, 289-293 (A06313-17), 294-306, 307-308, (A06318-19), 309-312				FRE 402, 403, 802	
523	Hardy, JG "Intranasal Drug Delivery by Spray and Dros." J. Pharm Pharmacol. Vol. 37, 1985:294-297				FRE 402, 403, 802	
524	Defendants' Deposition Exhibit 53A				FRE 402, 403, 802	
525	Defendants' Deposition Exhibit 53B				FRE 402, 403, 802	
526	Stipulated Findings of Fact					
527	Black's Medical Dictionary; pp. 540, 589.				FRE 402, 403, 802	
528	Random House Dictionary; pp. 102, 222, 326, 431, 456, 559, 620, 1194, 1651.				FRE 402, 403, 802	

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				No Obj.	Objection Basis	
529	McGraw-Hill Dictionary of Chemical Terms. Ed. Parker. New York: McGraw-Hill, 1985. pp. 31, 152, 400.				FRE 402, 403, 802	
530	Grant and Hackh's Chemical Dictionary; pp. 373.				FRE 402, 403, 802	
531	Ansel, "Introduction to Pharmaceutical Dosage Forms." (1985); pp. 325, 338.				FRE 402, 403, 802	
532	Physician's Desk Reference (1987); p. 928.				FRE 402, 403, 802	
533	ANDA-related Correspondence	A 007912-007921; A 007941-008131; A 008147-008153; A 008292-008320			FRE 402, 403, 802	
534	Deficiency Letter	A 007932-007940			FRE 402, 403, 802	
535	Response to Deficiency Letter	A 008379-008596			FRE 402, 403, 802	

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PTX	Description	Bates Range	PDX	Admission No Obj.	Objection Basis	Date Admitted
536	ANDA No. 77-954	A 000942-003287, A 005060-005065, A 005146-005151, A 005247-005249, A 005252, A 005255			FRE 402, 403, 802	
537	Excerpt from Expert Report of Dr. Bym reviewed by Dr. Meltzer and Dr. Dalby				FRE 402, 403, 802	
538	Excerpt from Expert Report of Dr. Bym reviewed by Dr. Dalby				FRE 402, 403, 802	
539	Excerpt from Expert Report of Dr. Meltzer reviewed by Dr. Dalby				FRE 402, 403, 802	
540	Excerpt from Expert Report of Dr. Dalby reviewed by Dr. Bym				FRE 402, 403, 802	
541	Excerpt from Expert Report of Dr. Meltzer reviewed by Dr. Bym				FRE 402, 403, 802	
4000	Physical Exhibits				FRE 402, 403, 802	
5000	Demonstratives				FRE 402, 403, 802	